



Clinical trial results:

A Phase II, open-label, randomised controlled study to evaluate the safety, reactogenicity and immunogenicity of GSK Biologicals' candidate tuberculosis (TB) vaccine (M72/AS01E) when administered intramuscularly according to different immunisation schedules to healthy infants, living in a TB-endemic region

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2012-004380-44 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 16 March 2012 |

Results information

| | |
|--------------------------------|---|
| Result version number | v4 (current) |
| This version publication date | 19 April 2023 |
| First version publication date | 18 July 2015 |
| Version creation reason | <ul style="list-style-type: none">• Correction of full data set Correction of full data set and alignment between registries. |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 112899 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01098474 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | GlaxoSmithKline Biologicals, |
| Sponsor organisation address | Rue de l'Institut 89, Rixensart, Belgium, B-1330 |
| Public contact | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com |
| Scientific contact | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com |

Notes:

Paediatric regulatory details

| | |
|--|-----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | Yes |

Notes:

Results analysis stage

| | |
|--|---------------|
| Analysis stage | Final |
| Date of interim/final analysis | 17 July 2012 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 30 April 2011 |
| Global end of trial reached? | Yes |
| Global end of trial date | 16 March 2012 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety of 1 or 2 doses of the TB candidate vaccine when given to healthy infants concomitantly with the EPI regimen containing the DTPw-HBV/Hib, 7Pn and OPV vaccines.
To evaluate the safety of 1 or 2 doses of the TB candidate vaccine when given to healthy infants after receiving the EPI vaccines containing the DTPw-HBV/Hib, 7Pn and OPV vaccines.

Protection of trial subjects:

All subjects were supervised after vaccination/product administration with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 07 July 2010 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety |
| Long term follow-up duration | 12 Months |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | Gambia: 301 |
| Worldwide total number of subjects | 301 |
| EEA total number of subjects | 0 |

Notes:

Subjects enrolled per age group

| | |
|---|-----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 301 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |

| | |
|---------------------|---|
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

One enrolled subject was not administered any vaccine and hence was not considered as having started the study.

Pre-assignment period milestones

| | |
|----------------------------|-----|
| Number of subjects started | 301 |
|----------------------------|-----|

| | |
|------------------------------|-----|
| Number of subjects completed | 300 |
|------------------------------|-----|

Pre-assignment subject non-completion reasons

| | |
|----------------------------|----------------------------|
| Reason: Number of subjects | No vaccination received: 1 |
|----------------------------|----------------------------|

Period 1

| | |
|----------------|--------------|
| Period 1 title | Active Phase |
|----------------|--------------|

| | |
|------------------------------|-----|
| Is this the baseline period? | Yes |
|------------------------------|-----|

| | |
|-------------------|-------------------------|
| Allocation method | Randomised - controlled |
|-------------------|-------------------------|

| | |
|---------------|-------------|
| Blinding used | Not blinded |
|---------------|-------------|

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|-----------------------|
| Arm title | SB692342 2 dose Group |
|------------------|-----------------------|

Arm description:

Subjects received two doses of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, 1 month apart, on a 0, 1 month schedule after having completed their primary EPI regimen.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|--|
| Investigational medicinal product name | GSK Biologicals' candidate tuberculosis vaccine (692342) |
|--|--|

| | |
|--|--|
| Investigational medicinal product code | |
|--|--|

| | |
|------------|----------|
| Other name | SB692342 |
|------------|----------|

| | |
|----------------------|-----------|
| Pharmaceutical forms | Injection |
|----------------------|-----------|

| | |
|--------------------------|-------------------|
| Routes of administration | Intramuscular use |
|--------------------------|-------------------|

Dosage and administration details:

Two doses of 0,5 mL vaccine were administered intramuscularly in the anterolateral region of the right thigh, on a 0, 1 month schedule after having completed their primary EPI regimen.

| | |
|------------------|-----------------------|
| Arm title | SB692342 1 dose Group |
|------------------|-----------------------|

Arm description:

Subjects received one dose of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, at Month 0, after having completed their primary EPI regimen.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|--|
| Investigational medicinal product name | GSK Biologicals' candidate tuberculosis vaccine (692342) |
|--|--|

| | |
|--|--|
| Investigational medicinal product code | |
|--|--|

| | |
|------------|----------|
| Other name | SB692342 |
|------------|----------|

| | |
|----------------------|-----------|
| Pharmaceutical forms | Injection |
|----------------------|-----------|

| | |
|--------------------------|-------------------|
| Routes of administration | Intramuscular use |
|--------------------------|-------------------|

Dosage and administration details:

One dose of 0,5 mL vaccine was administered intramuscularly in the anterolateral region of the right thigh, at Month 0, after having completed their primary EPI regimen.

| | |
|------------------|-------------------------|
| Arm title | Control Menjugate Group |
|------------------|-------------------------|

Arm description:

Subjects received three doses of the control Menjugate vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, on a 0, 1, 7 months schedule. The first two doses were administered 1 month apart during the primary vaccination phase and the third dose was administered 6 months after the last primary vaccination dose.

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Menjugate |
| Investigational medicinal product code | |
| Other name | MenC |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Three doses of the 0,5 mL control vaccine were administered intramuscularly in the anterolateral region of the right thigh, on a 0, 1, 7 months schedule. The first 2 doses were administered 1 month apart during the primary vaccination phase and the third dose was administered 6 months after the last primary vaccination dose.

| | |
|------------------|--|
| Arm title | SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group |
|------------------|--|

Arm description:

Subjects received two doses of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, 1 month apart, concomitantly with the last two doses of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered intramuscularly in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Prevnar vaccine, administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Prevnar vaccines approximately 1 year after their last dose.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | GSK Biologicals' candidate tuberculosis vaccine (692342) |
| Investigational medicinal product code | |
| Other name | SB692342 |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two doses of GSK's investigational vaccine 692342 (0,5 mL) were administered, 1 Month apart, intramuscularly in the anterolateral region of the right thigh, concomitantly with the last two doses of the primary EPI regimen containing Tritanrix, HepB+Hiberix, Polio Sabin and Prevnar, on a 1, 2 months schedule.

| | |
|--|------------------------|
| Investigational medicinal product name | Tritanrix HepB+Hiberix |
| Investigational medicinal product code | |
| Other name | DTPw-HBV/Hib |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

The last two doses of the primary EPI regimen containing Tritanrix HepB+Hiberix, received intramuscularly in the anterolateral region of the left thigh, Polio Sabin and Prevnar were administered together with two doses of GSK's investigational vaccine 692342, on a 1, 2 months schedule.

| | |
|--|-------------|
| Investigational medicinal product name | Polio Sabin |
| Investigational medicinal product code | |
| Other name | OPV |

| | |
|--------------------------|--------------------------|
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Oral use |

Dosage and administration details:

The last two doses of the primary EPI regimen containing Tritanrix HepB+Hiberix, Polio Sabin received orally and Pevnar were administered together with two doses of GSK's investigational vaccine 692342, on a 1, 2 months schedule.

| | |
|--|-------------------|
| Investigational medicinal product name | Pevnar |
| Investigational medicinal product code | |
| Other name | 7Pn |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

The last two doses of the primary EPI regimen containing Tritanrix HepB+Hiberix, Polio Sabin and Pevnar received intramuscularly in the right arm, were administered together with two doses of GSK's investigational vaccine 692342, on a 1, 2 months schedule.

| | |
|------------------|--|
| Arm title | SB692392 1 dose +Tritanrix + Pevnar+ Polio Sabin Group |
|------------------|--|

Arm description:

Subjects received one dose of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, concomitantly with the last dose of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered intramuscularly in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Pevnar vaccine, administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Pevnar vaccines approximately 1 year after their last dose.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | GSK Biologicals' candidate tuberculosis vaccine (692342) |
| Investigational medicinal product code | |
| Other name | SB692342 |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One dose of GSK's investigational vaccine 692342 (0,5 mL) was administered, intramuscularly in the anterolateral region of the right thigh, concomitantly with the last dose of the primary EPI regimen containing Tritanrix, HepB+Hiberix, Polio Sabin and Pevnar, at month 2.

| | |
|--|------------------------|
| Investigational medicinal product name | Tritanrix HepB+Hiberix |
| Investigational medicinal product code | |
| Other name | DTPw-HBV/Hib |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

The last dose of the primary EPI regimen containing Tritanrix HepB+Hiberix, received intramuscularly in the anterolateral region of the left thigh, Polio Sabin and Pevnar was administered together with one dose of GSK's investigational vaccine 692342, at month 2.

| | |
|--|--------------------------|
| Investigational medicinal product name | Polio Sabin |
| Investigational medicinal product code | |
| Other name | OPV |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Oral use |

Dosage and administration details:

The last dose of the primary EPI regimen containing Tritanrix HepB+Hiberix, Polio Sabin received orally and Pevnar was administered together with one dose of GSK's investigational vaccine 692342, at month 2.

| | |
|--|-----------|
| Investigational medicinal product name | Pevnar |
| Investigational medicinal product code | |
| Other name | 7Pn |
| Pharmaceutical forms | Injection |

| | |
|--------------------------|-------------------|
| Routes of administration | Intramuscular use |
|--------------------------|-------------------|

Dosage and administration details:

The last dose of the primary EPI regimen containing Tritanrix HepB+Hiberix, Polio Sabin and Pevnar received intramuscularly in the right arm, was administered together with one dose of GSK's investigational vaccine 692342, at month 2.

| | |
|------------------|--|
| Arm title | Control Tritanrix + Pevnar + Polio Sabin Group |
|------------------|--|

Arm description:

Subjects received three doses of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Pevnar vaccine administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Pevnar vaccines approximately 1 year after their last dose.

| | |
|--|------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Tritanrix HepB+Hiberix |
| Investigational medicinal product code | |
| Other name | DTPw-HBV/Hib |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Three doses of the primary EPI regimen containing Tritanrix HepB+Hiberix, Polio Sabin and Pevnar were administered on a 0, 1, 2 Months schedule.

| | |
|--|-------------------|
| Investigational medicinal product name | Pevnar |
| Investigational medicinal product code | |
| Other name | 7Pn |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Three doses of the primary EPI regimen containing Tritanrix HepB+Hiberix, Polio Sabin and Pevnar were administered on a 0, 1, 2 Months schedule.

| | |
|--|--------------------------|
| Investigational medicinal product name | Polio Sabin |
| Investigational medicinal product code | |
| Other name | OPV |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Oral use |

Dosage and administration details:

Three doses of the primary EPI regimen containing Tritanrix HepB+Hiberix, Polio Sabin and Pevnar were administered on a 0, 1, 2 Months schedule.

| Number of subjects in period 1^[1] | SB692342 2 dose Group | SB692342 1 dose Group | Control Menjugate Group |
|---|-----------------------|-----------------------|-------------------------|
| Started | 50 | 50 | 50 |
| Completed | 48 | 49 | 45 |
| Not completed | 2 | 1 | 5 |
| Consent withdrawn by subject | 1 | 1 | 2 |
| Unspecified | - | - | 3 |
| Lost to follow-up | 1 | - | - |

| Number of subjects in period 1^[1] | SB692392 2dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose +Tritanrix + Pevnar+ Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group |
|---|--|---|---|
| Started | 49 | 52 | 49 |
| Completed | 49 | 52 | 49 |
| Not completed | 0 | 0 | 0 |
| Consent withdrawn by subject | - | - | - |
| Unspecified | - | - | - |
| Lost to follow-up | - | - | - |

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: One enrolled subject was not administered any vaccine and hence was not considered as having started the study.

Period 2

| | |
|------------------------------|-------------------------|
| Period 2 title | Follow-up Phase |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|---|
| Are arms mutually exclusive? | Yes |
| Arm title | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group |

Arm description:

Subjects received two doses of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, 1 month apart, concomitantly with the last two doses of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered intramuscularly in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Pevnar vaccine, administered intramuscularly in the right arm, on a 0, 1, 2 months schedule.

All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Pevnar vaccines approximately 1 year after their last dose.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | GSK Biologicals' candidate tuberculosis vaccine (692342) |
| Investigational medicinal product code | |
| Other name | SB692342 |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two doses of GSK's investigational vaccine 692342 (0,5 mL) were administered, 1 Month apart, intramuscularly in the anterolateral region of the right thigh, concomitantly with the last two doses of the primary EPI regimen containing Tritanrix, HepB+Hiberix, Polio Sabin and Pevnar, at month 1 and 2 during the active phase.

| | |
|--|------------------------|
| Investigational medicinal product name | Tritanrix HepB+Hiberix |
| Investigational medicinal product code | |
| Other name | DTPw-HBV/Hib |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

The last two doses of the primary EPI regimen containing Tritanrix HepB+Hiberix, received intramuscularly in the anterolateral region of the left thigh, Polio Sabin and Pevnar were administered together with two doses of GSK's investigational vaccine 692342.

All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Pevnar vaccines approximately 1 year after their last dose.

| | |
|--|--------------------------|
| Investigational medicinal product name | Polio Sabin |
| Investigational medicinal product code | |
| Other name | OPV |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Oral use |

Dosage and administration details:

The last two doses of the primary EPI regimen containing Tritanrix HepB+Hiberix, Polio Sabin received orally and Prevnar were administered together with two doses of GSK's investigational vaccine 692342. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Prevnar vaccines approximately 1 year after their last dose.

| | |
|--|-------------------|
| Investigational medicinal product name | Prevnar |
| Investigational medicinal product code | |
| Other name | 7Pn |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

The last two doses of the primary EPI regimen containing Tritanrix HepB+Hiberix, Polio Sabin and Prevnar received intramuscularly in the right arm, were administered together with two doses of GSK's investigational vaccine 692342.

All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Prevnar vaccines approximately 1 year after their last dose.

| | |
|------------------|---|
| Arm title | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group |
|------------------|---|

Arm description:

Subjects received one dose of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, concomitantly with the last dose of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered intramuscularly in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Prevnar vaccine, administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Prevnar vaccines approximately 1 year after their last dose.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | GSK Biologicals' candidate tuberculosis vaccine (692342) |
| Investigational medicinal product code | |
| Other name | SB692342 |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One dose of GSK's investigational vaccine 692342 (0,5 mL) was were administered, 1 Month apart, intramuscularly in the anterolateral region of the right thigh, concomitantly with the last dose of the primary EPI regimen containing Tritanrix™ HepB+Hiberix™, Polio Sabin™ administered orally and Prevnar® administered intramuscularly in the right arm.

| | |
|--|------------------------|
| Investigational medicinal product name | Tritanrix HepB+Hiberix |
| Investigational medicinal product code | |
| Other name | DTPw-HBV/Hib |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

The last dose of the primary EPI regimen containing Tritanrix HepB+Hiberix, received intramuscularly in the anterolateral region of the left thigh, Polio Sabin and Prevnar were administered together with one dose of GSK's investigational vaccine 692342.

| | |
|--|--------------------------|
| Investigational medicinal product name | Polio Sabin |
| Investigational medicinal product code | |
| Other name | OPV |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Oral use |

| | |
|---|-------------------|
| Dosage and administration details: | |
| The last dose of the primary EPI regimen containing Tritanrix HepB+Hiberix , Polio Sabin received orally and Pevnar were administered together with one dose of GSK's investigational vaccine 692342. | |
| Investigational medicinal product name | Pevnar |
| Investigational medicinal product code | |
| Other name | 7Pn |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

The last dose of the primary EPI regimen containing Tritanrix HepB+Hiberix, Polio Sabin and Pevnar received intramuscularly in the right arm, were administered together with one dose of GSK's investigational vaccine 692342.

| | |
|------------------|--|
| Arm title | Control Tritanrix + Pevnar + Polio Sabin Group |
|------------------|--|

Arm description:

Subjects received three doses of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Pevnar vaccine administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Pevnar vaccines approximately 1 year after their last dose.

| | |
|--|------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Tritanrix HepB+Hiberix |
| Investigational medicinal product code | |
| Other name | DTPw-HBV/Hib |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Three doses of the primary EPI regimen containing Tritanrix HepB+Hiberix, Polio Sabin and Pevnar were administered on a 0, 1, 2 Months schedule.

| | |
|--|-------------------|
| Investigational medicinal product name | Pevnar |
| Investigational medicinal product code | |
| Other name | 7Pn |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Three doses of the primary EPI regimen containing Tritanrix HepB+Hiberix, Polio Sabin and Pevnar were administered on a 0, 1, 2 Months schedule.

| | |
|--|--------------------------|
| Investigational medicinal product name | Polio Sabin |
| Investigational medicinal product code | |
| Other name | OPV |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Oral use |

Dosage and administration details:

Three doses of the primary EPI regimen containing Tritanrix HepB+Hiberix, Polio Sabin and Pevnar were administered on a 0, 1, 2 Months schedule.

| | |
|------------------|-----------------------|
| Arm title | SB692342 2 dose Group |
|------------------|-----------------------|

Arm description:

Subjects received two doses of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, 1 month apart, on a 0, 1 month schedule after having completed their primary EPI regimen.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|--|
| Investigational medicinal product name | GSK Biologicals' candidate tuberculosis vaccine (692342) |
| Investigational medicinal product code | |
| Other name | SB692342 |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two doses of 0,5 mL vaccine were administered intramuscularly in the anterolateral region of the right thigh, on a 0, 1 month schedule after having completed their primary EPI regimen.

| | |
|------------------|-----------------------|
| Arm title | SB692342 1 dose Group |
|------------------|-----------------------|

Arm description:

Subjects received one dose of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, at Month 0, after having completed their primary EPI regimen.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | GSK Biologicals' candidate tuberculosis vaccine (692342) |
| Investigational medicinal product code | |
| Other name | SB692342 |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One dose of 0,5 mL vaccine was administered intramuscularly in the anterolateral region of the right thigh, at Month 0, after having completed their primary EPI regimen.

| | |
|------------------|-------------------------|
| Arm title | Control Menjugate Group |
|------------------|-------------------------|

Arm description:

Subjects received three doses of the control Menjugate vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, on a 0, 1, 7 months schedule. The first two doses were administered 1 month apart during the primary vaccination phase and the third dose was administered 6 months after the last primary vaccination dose.

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Menjugate |
| Investigational medicinal product code | |
| Other name | MenC |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Three doses of 0,5 mL control vaccine were administered intramuscularly in the anterolateral region of the right thigh, on a 0, 1, 7 months schedule. The first 2 doses were administered 1 month apart during the primary vaccination phase and the third dose was administered 6 months after the last primary vaccination dose.

| Number of subjects in period 2 | SB692392 2 dose + Tritanrix + Prevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group | Control Tritanrix + Prevnar + Polio Sabin Group |
|---------------------------------------|---|---|---|
| Started | 49 | 52 | 49 |
| Completed | 47 | 50 | 44 |
| Not completed | 2 | 2 | 5 |
| Consent withdrawn by subject | 2 | - | 1 |
| Travelled out of study area | - | 1 | - |
| Unspecified | - | - | 4 |

| | | | |
|-------------------|---|---|---|
| Lost to follow-up | - | 1 | - |
|-------------------|---|---|---|

| Number of subjects in period 2 | SB692342 2 dose Group | SB692342 1 dose Group | Control Menjugate Group |
|---------------------------------------|-----------------------|-----------------------|-------------------------|
| Started | 48 | 49 | 45 |
| Completed | 48 | 49 | 45 |
| Not completed | 0 | 0 | 0 |
| Consent withdrawn by subject | - | - | - |
| Travelled out of study area | - | - | - |
| Unspecified | - | - | - |
| Lost to follow-up | - | - | - |

Baseline characteristics

Reporting groups

| | |
|-----------------------|-----------------------|
| Reporting group title | SB692342 2 dose Group |
|-----------------------|-----------------------|

Reporting group description:

Subjects received two doses of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, 1 month apart, on a 0, 1 month schedule after having completed their primary EPI regimen.

| | |
|-----------------------|-----------------------|
| Reporting group title | SB692342 1 dose Group |
|-----------------------|-----------------------|

Reporting group description:

Subjects received one dose of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, at Month 0, after having completed their primary EPI regimen.

| | |
|-----------------------|-------------------------|
| Reporting group title | Control Menjugate Group |
|-----------------------|-------------------------|

Reporting group description:

Subjects received three doses of the control Menjugate vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, on a 0, 1, 7 months schedule. The first two doses were administered 1 month apart during the primary vaccination phase and the third dose was administered 6 months after the last primary vaccination dose.

| | |
|-----------------------|---|
| Reporting group title | SB692392 2dose + Tritanrix + Pevnar + Polio Sabin Group |
|-----------------------|---|

Reporting group description:

Subjects received two doses of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, 1 month apart, concomitantly with the last two doses of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered intramuscularly in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Pevnar vaccine, administered intramuscularly in the right arm, on a 0, 1, 2 months schedule.

All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Pevnar vaccines approximately 1 year after their last dose.

| | |
|-----------------------|--|
| Reporting group title | SB692392 1 dose +Tritanrix + Pevnar+ Polio Sabin Group |
|-----------------------|--|

Reporting group description:

Subjects received one dose of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, concomitantly with the last dose of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered intramuscularly in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Pevnar vaccine, administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Pevnar vaccines approximately 1 year after their last dose.

| | |
|-----------------------|--|
| Reporting group title | Control Tritanrix + Pevnar + Polio Sabin Group |
|-----------------------|--|

Reporting group description:

Subjects received three doses of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Pevnar vaccine administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Pevnar vaccines approximately 1 year after their last dose.

| Reporting group values | SB692342 2 dose Group | SB692342 1 dose Group | Control Menjugate Group |
|--|-----------------------|-----------------------|-------------------------|
| Number of subjects | 50 | 50 | 50 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |

| | | | |
|--|--------|--------|--------|
| Infants and toddlers (28 days-23 months) | 50 | 50 | 50 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age continuous | | | |
| Units: months | | | |
| arithmetic mean | 5.8 | 5.7 | 5.7 |
| standard deviation | ± 0.68 | ± 0.61 | ± 0.65 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 34 | 20 | 23 |
| Male | 16 | 30 | 27 |

| Reporting group values | SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group | SB692392 1 dose +Tritanrix + Prevnar+ Polio Sabin Group | Control Tritanrix + Prevnar + Polio Sabin Group |
|---|--|--|---|
| Number of subjects | 49 | 52 | 49 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 49 | 52 | 49 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age continuous | | | |
| Units: months | | | |
| arithmetic mean | 2.1 | 2 | 2.1 |
| standard deviation | ± 0.28 | ± 0.19 | ± 0.31 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 25 | 16 | 23 |
| Male | 24 | 36 | 26 |

| Reporting group values | Total | | |
|---|-------|--|--|
| Number of subjects | 300 | | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | | |
| Newborns (0-27 days) | 0 | | |
| Infants and toddlers (28 days-23 months) | 300 | | |
| Children (2-11 years) | 0 | | |

| | | | |
|---------------------------|-----|--|--|
| Adolescents (12-17 years) | 0 | | |
| Adults (18-64 years) | 0 | | |
| From 65-84 years | 0 | | |
| 85 years and over | 0 | | |
| Age continuous | | | |
| Units: months | | | |
| arithmetic mean | | | |
| standard deviation | - | | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 141 | | |
| Male | 159 | | |

End points

End points reporting groups

| | |
|---|---|
| Reporting group title | SB692342 2 dose Group |
| Reporting group description: Subjects received two doses of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, 1 month apart, on a 0, 1 month schedule after having completed their primary EPI regimen. | |
| Reporting group title | SB692342 1 dose Group |
| Reporting group description: Subjects received one dose of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, at Month 0, after having completed their primary EPI regimen. | |
| Reporting group title | Control Menjugate Group |
| Reporting group description: Subjects received three doses of the control Menjugate vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, on a 0, 1, 7 months schedule. The first two doses were administered 1 month apart during the primary vaccination phase and the third dose was administered 6 months after the last primary vaccination dose. | |
| Reporting group title | SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group |
| Reporting group description: Subjects received two doses of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, 1 month apart, concomitantly with the last two doses of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered intramuscularly in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Prevnar vaccine, administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Prevnar vaccines approximately 1 year after their last dose. | |
| Reporting group title | SB692392 1 dose +Tritanrix + Prevnar+ Polio Sabin Group |
| Reporting group description: Subjects received one dose of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, concomitantly with the last dose of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered intramuscularly in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Prevnar vaccine, administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Prevnar vaccines approximately 1 year after their last dose. | |
| Reporting group title | Control Tritanrix + Prevnar + Polio Sabin Group |
| Reporting group description: Subjects received three doses of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Prevnar vaccine administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Prevnar vaccines approximately 1 year after their last dose. | |
| Reporting group title | SB692392 2 dose + Tritanrix + Prevnar + Polio Sabin Group |
| Reporting group description: Subjects received two doses of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, 1 month apart, concomitantly with the last two doses of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered intramuscularly in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Prevnar vaccine, administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Prevnar vaccines approximately 1 year after their last dose. | |
| Reporting group title | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group |
| Reporting group description: Subjects received one dose of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, concomitantly with the last dose of the primary EPI regimen | |

containing Tritanrix HepB+Hiberix vaccine, administered intramuscularly in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Prevnar vaccine, administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Prevnar vaccines approximately 1 year after their last dose.

| | |
|-----------------------|---|
| Reporting group title | Control Tritanrix + Prevnar + Polio Sabin Group |
|-----------------------|---|

Reporting group description:

Subjects received three doses of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Prevnar vaccine administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Prevnar vaccines approximately 1 year after their last dose.

| | |
|-----------------------|-----------------------|
| Reporting group title | SB692342 2 dose Group |
|-----------------------|-----------------------|

Reporting group description:

Subjects received two doses of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, 1 month apart, on a 0, 1 month schedule after having completed their primary EPI regimen.

| | |
|-----------------------|-----------------------|
| Reporting group title | SB692342 1 dose Group |
|-----------------------|-----------------------|

Reporting group description:

Subjects received one dose of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, at Month 0, after having completed their primary EPI regimen.

| | |
|-----------------------|-------------------------|
| Reporting group title | Control Menjugate Group |
|-----------------------|-------------------------|

Reporting group description:

Subjects received three doses of the control Menjugate vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, on a 0, 1, 7 months schedule. The first two doses were administered 1 month apart during the primary vaccination phase and the third dose was administered 6 months after the last primary vaccination dose.

Primary: Number of subjects with grade 3 solicited local symptoms after dose 1, dose 2 and across doses

| | |
|-----------------|--|
| End point title | Number of subjects with grade 3 solicited local symptoms after dose 1, dose 2 and across doses ^{[1][2]} |
|-----------------|--|

End point description:

Solicited local symptoms assessed were pain, redness and swelling. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 20 millimeters (mm) of injection site.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Day 0 to Day 6

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692342 1 dose Group | Control Menjugate Group | |
|---------------------------------------|-----------------------|-----------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 50 | 50 | 50 | |
| Units: Subjects | | | | |
| Grade 3 Pain, D1 (N=50,50,50) | 0 | 0 | 0 | |
| Grade 3 Swelling, D1 (N=50,50,50) | 0 | 0 | 0 | |
| Grade 3 Pain, D2 (N=49,0 ,48) | 0 | 0 | 0 | |
| Grade 3 Swelling, D2 (N=49,0,48) | 0 | 0 | 0 | |
| Grade 3 Pain, Across (N=50,50,50) | 0 | 0 | 0 | |
| Grade 3 Swelling, Across (N=50,50,50) | 0 | 0 | 0 | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 solicited local symptoms after dose 2, dose 3 and across doses

| | |
|-----------------|---|
| End point title | Number of subjects with grade 3 solicited local symptoms after dose 2, dose 3 and across doses ^[3] |
|-----------------|---|

End point description:

Solicited local symptoms were only collected after Dose 2 of EPI vaccination. Solicited local symptoms assessed were pain, redness and swelling. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 20 millimeters (mm) of injection site.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Day 0 to Day 6

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | SB692392 2 dose + Tritanrix + Prevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group | Control Tritanrix + Prevnar + Polio Sabin Group | |
|---------------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 47 | 52 | 48 | |
| Units: Subjects | | | | |
| Grade 3 Pain, D2 (N=47,0 ,47) | 0 | 0 | 0 | |
| Grade 3 Swelling, D2 (N=47,0,47) | 2 | 0 | 2 | |
| Grade 3 Pain, D3 (N=47,52,48) | 2 | 0 | 0 | |
| Grade 3 Swelling, D3 (N=47,52,48) | 3 | 6 | 3 | |
| Grade 3 Pain, Across (N=47,52,48) | 2 | 0 | 0 | |
| Grade 3 Swelling, Across (N=47,52,48) | 3 | 6 | 5 | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 solicited general symptoms after dose 1, dose 2 and across doses

| | |
|-----------------|--|
| End point title | Number of subjects with grade 3 solicited general symptoms after dose 1, dose 2 and across doses ^[4] ^[5] |
|-----------------|--|

End point description:

Solicited general symptoms assessed were drowsiness, fever [defined as axillary temperature equal to or above 37.5 degrees Celsius (°C)], irritability/fussiness and loss of appetite. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.0 °C.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Day 0 to Day 6

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692342 1 dose Group | Control Menjugate Group | |
|--|-----------------------|-----------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 50 | 50 | 50 | |
| Units: Subjects | | | | |
| Grade 3 Drowsiness, D1 (N=50,50,50) | 0 | 0 | 0 | |
| Grade 3 Irritability, D1 (N=50,50,50) | 0 | 0 | 0 | |
| Grade 3 Loss of appetite, D1 (N=50,50,50) | 0 | 0 | 0 | |
| Grade 3 Temperature /Axillary, D1 (N=50,50,50) | 0 | 0 | 0 | |
| Grade 3 Drowsiness, D2 (N=49,0 ,48) | 0 | 0 | 0 | |
| Grade 3 Irritability, D2 (N=49,0,48) | 0 | 0 | 0 | |
| Grade 3 Loss of appetite, D2 (N=49,0,48) | 0 | 0 | 0 | |
| Grade 3 Temperature/Axillary, D2 (N=49,0,48) | 0 | 0 | 1 | |
| Grade 3 Drowsiness, Across (N=50,50,50) | 0 | 0 | 0 | |
| Grade 3 Irritability, Across (N=50,50,50) | 0 | 0 | 0 | |
| Grade 3 Loss of appetite, Across (N=50,50,50) | 0 | 0 | 0 | |
| Grade 3 Fever/Axillary, Across (N=50,50,50) | 0 | 0 | 1 | |

Statistical analyses

Primary: Number of subjects with grade 3 solicited general symptoms after dose 2, dose 3 and across doses

| | |
|-----------------|---|
| End point title | Number of subjects with grade 3 solicited general symptoms after dose 2, dose 3 and across doses ^[6] |
|-----------------|---|

End point description:

Solicited general symptoms were only collected after Dose 2 of EPI vaccination. Solicited general symptoms assessed were drowsiness, fever [defined as axillary temperature equal to or above 37.5 degrees Celsius (°C)], irritability/fussiness and loss of appetite. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.0 °C.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Day 0 to Day 6

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | SB692392 2 dose + Tritanrix + Prevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group | Control Tritanrix + Prevnar + Polio Sabin Group | |
|---|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 47 | 52 | 48 | |
| Units: Subjects | | | | |
| Grade 3 Drowsiness, D2 (N=47,0 ,47) | 0 | 0 | 0 | |
| Grade 3 Irritability, D2 (N=47,0,47) | 0 | 0 | 0 | |
| Grade 3 Loss of appetite, D2 (N=47,0,47) | 0 | 0 | 0 | |
| Grade 3 Temperature/Axillary, D2 (N=47,0,47) | 0 | 0 | 0 | |
| Grade 3 Drowsiness, D3 (N=47,52,48) | 0 | 0 | 0 | |
| Grade 3 Irritability, D3 (N=47,52,48) | 2 | 0 | 0 | |
| Grade 3 Loss of appetite, D3 (N=47,52,48) | 0 | 0 | 0 | |
| Grade 3 Temperature/Axillary, D3 (N=47,52,48) | 0 | 0 | 0 | |
| Grade 3 Drowsiness, Across (N=47,52,48) | 0 | 0 | 0 | |
| Grade 3 Irritability, Across (N=47,52,48) | 2 | 0 | 0 | |
| Grade 3 Loss of appetite, Across (N=47,52,48) | 0 | 0 | 0 | |
| Grade 3 Fever/Axillary, Across (N=47,52,48) | 0 | 0 | 0 | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 unsolicited adverse events (AEs)

| | |
|-----------------|--|
| End point title | Number of subjects with grade 3 unsolicited adverse events (AEs) ^{[7][8]} |
|-----------------|--|

End point description:

An unsolicited adverse event is any untoward medical occurrence in a clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Day 0 to Day 29

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group |
|-----------------------------|-----------------------|--|-----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 50 | 47 | 50 | 52 |
| Units: Subjects | | | | |
| Grade 3 AEs | 28 | 25 | 27 | 14 |

| End point values | Control Menjugate Group | Control Tritanrix + Pevnar + Polio Sabin Group | | |
|-----------------------------|-------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 50 | 48 | | |
| Units: Subjects | | | | |
| Grade 3 AEs | 26 | 22 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with serious adverse events (SAEs)

| | |
|-----------------|--|
| End point title | Number of subjects with serious adverse events (SAEs) ^{[9][10]} |
|-----------------|--|

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life-threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Month 0 to Month 17

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group |
|-----------------------------|-----------------------|--|-----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 50 | 49 | 50 | 52 |
| Units: Subjects | | | | |
| Any SAEs | 0 | 1 | 0 | 0 |

| End point values | Control Menjugate Group | Control Tritanrix + Pevnar + Polio Sabin Group | | |
|-----------------------------|-------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 50 | 49 | | |
| Units: Subjects | | | | |
| Any SAEs | 1 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

| | |
|-----------------|---|
| End point title | Number of subjects with grade 3 haematological and biochemical levels ^{[11][12]} |
|-----------------|---|

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA). Grade 3 = Haem.: lesser than (<) 5.0 grams per deciliter (g/dL); WBC.: 1.0 to 1.4 x 10³/micro liter (µL); PLA.: < 25x10³/µL; ALA.: 5.1 to 10.0 x upper limit of normal (ULN) and CREA: 3.1 to 6.0 x ULN.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At Day 0

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group |
|-----------------------------|-----------------------|--|-----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 50 | 49 | 50 | 52 |
| Units: Subjects | | | | |
| Haem, PRE, Grade 3 | 0 | 0 | 0 | 0 |
| WBC, PRE, Grade 3 | 0 | 0 | 0 | 0 |
| PLA, PRE, Grade 3 | 0 | 0 | 0 | 0 |
| ALA, PRE, Grade 3 | 0 | 0 | 0 | 0 |
| CREA PRE, Grade 3 | 0 | 0 | 0 | 0 |

| End point values | Control Menjugate Group | Control Tritanrix + Pevnar + Polio Sabin Group | | |
|-----------------------------|-------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 50 | 49 | | |
| Units: Subjects | | | | |
| Haem, PRE, Grade 3 | 0 | 0 | | |
| WBC, PRE, Grade 3 | 0 | 0 | | |
| PLA, PRE, Grade 3 | 0 | 0 | | |
| ALA, PRE, Grade 3 | 0 | 0 | | |
| CREA PRE, Grade 3 | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

| | |
|---|---|
| End point title | Number of subjects with grade 3 haematological and biochemical levels ^{[13][14]} |
| End point description: Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA). Grade 3 = Haem.: < 5.0 g/dL; WBC.: 1.0 to 1.4 x 10 ³ /μL; PLA.: < 25x10 ³ /μL; ALA.: 5.1 to 10.0 x ULN and CREA: 3.1 to 6.0 x ULN. | |
| End point type | Primary |

End point timeframe:

Seven days post Dose 1, at Day 7 [PI(D7)]

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692342 1 dose Group | Control Menjugate Group | |
|-----------------------------|-----------------------|-----------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 50 | 50 | 50 | |
| Units: Subjects | | | | |
| Haem, PI(D7), Grade 3 | 0 | 0 | 0 | |
| WBC, PI(D7) Grade 3 | 0 | 0 | 0 | |
| PLA, PI(D7), Grade 3 | 0 | 0 | 0 | |
| ALA, PI(D7), Grade 3 | 0 | 0 | 0 | |
| CREA PI(D7), Grade 3 | 0 | 0 | 0 | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

| | |
|-----------------|---|
| End point title | Number of subjects with grade 3 haematological and biochemical levels ^{[15][16]} |
|-----------------|---|

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA). Grade 3 = Haem.: < 5.0 g/dL; WBC.: 1.0 to 1.4 x 10³/μL; PLA.: < 25x10³/μL; ALA.: 5.1 to 10.0 x ULN and CREA: 3.1 to 6.0 x ULN.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Seven days post Dose 2, at Day 37 [PII(D37)]

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Menjugate Group |
|-----------------------------|-----------------------|--|--|-------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 50 | 49 | 52 | 50 |
| Units: Subjects | | | | |
| Haem, PII(D37), Grade 3 | 0 | 0 | 0 | 0 |
| WBC, PII(D37) Grade 3 | 0 | 0 | 0 | 0 |
| PLA, PII(D37), Grade 3 | 0 | 0 | 0 | 0 |
| ALA, PII(D37), Grade 3 | 0 | 0 | 0 | 0 |
| CREA PII(D37), Grade 3 | 0 | 0 | 0 | 0 |

| End point values | Control Tritanrix + Pevnar + Polio Sabin Group | | | |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 49 | | | |
| Units: Subjects | | | | |
| Haem, PII(D37), Grade 3 | 0 | | | |
| WBC, PII(D37) Grade 3 | 0 | | | |
| PLA, PII(D37), Grade 3 | 0 | | | |
| ALA, PII(D37), Grade 3 | 0 | | | |
| CREA PII(D37), Grade 3 | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

| | |
|-----------------|---|
| End point title | Number of subjects with grade 3 haematological and biochemical levels ^[17] |
|-----------------|---|

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA). Grade 3 = Haem.: < 5.0 g/dL; WBC.: 1.0 to 1.4 x 10³/μL; PLA.: < 25x10³/μL; ALA.: 5.1 to 10.0 x ULN and CREA: 3.1 to 6.0 x ULN.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Seven days post Dose 3, at Day 67 [PIII(D67)]

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | SB692392 2 dose + Tritanrix + Prevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group | Control Tritanrix + Prevnar + Polio Sabin Group | |
|-----------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 52 | 49 | |
| Units: Subjects | | | | |
| Haem, PIII(D67), Grade 3 | 0 | 0 | 0 | |
| WBC, PIII(D67) Grade 3 | 0 | 0 | 0 | |
| PLA, PIII(D67), Grade 3 | 0 | 0 | 0 | |
| ALA, PIII(D67), Grade 3 | 0 | 0 | 0 | |
| CREA PIII(D67), Grade 3 | 0 | 0 | 0 | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

| | |
|-----------------|---|
| End point title | Number of subjects with grade 3 haematological and biochemical levels ^[18] ^[19] |
|-----------------|---|

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA). Grade 3 = Haem.: < 5.0 g/dL; WBC.: 1.0 to 1.4 x 10³/μL; PLA.: < 25x10³/μL; ALA.: 5.1 to 10.0 x ULN and CREA: 3.1 to 6.0 x ULN.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

One Month post Dose 1, at Month 1 [PI(M1)]

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692342 1 dose Group | Control Menjugate Group | |
|-----------------------------|-----------------------|-----------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 50 | 50 | 50 | |
| Units: Subjects | | | | |
| Haem, PI(M1), Grade 3 | 0 | 0 | 0 | |
| WBC, PI(M1) Grade 3 | 0 | 0 | 0 | |
| PLA, PI(M1), Grade 3 | 0 | 0 | 0 | |
| ALA, PI(M1), Grade 3 | 0 | 0 | 0 | |
| CREA PI(M1), Grade 3 | 0 | 0 | 0 | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

| | |
|-----------------|---|
| End point title | Number of subjects with grade 3 haematological and biochemical levels ^{[20][21]} |
|-----------------|---|

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA). Grade 3 = Haem.: < 5.0 g/dL; WBC.: 1.0 to 1.4 x 10³/μL; PLA.: < 25x10³/μL; ALA.: 5.1 to 10.0 x ULN and CREA: 3.1 to 6.0 x ULN.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

One Month post Dose 2, at Month 2 [PII(M2)]

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | Control Menjugate Group | | |
|-----------------------------|-----------------------|-------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 50 | 50 | | |
| Units: Subjects | | | | |
| Haem, PII(M2), Grade 3 | 0 | 0 | | |
| WBC, PII(M2) Grade 3 | 0 | 0 | | |
| PLA, PII(M2), Grade 3 | 0 | 0 | | |
| ALA, PII(M2), Grade 3 | 0 | 0 | | |
| CREA PII(M2), Grade 3 | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

| | |
|-----------------|---|
| End point title | Number of subjects with grade 3 haematological and biochemical levels ^[22] |
|-----------------|---|

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC),

Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA). Grade 3 = Haem.: < 5.0 g/dL; WBC.: 1.0 to 1.4 x 10³/μL; PLA.: < 25x10³/μL; ALA.: 5.1 to 10.0 x ULN and CREA: 3.1 to 6.0 x ULN.

| | |
|--|---------|
| End point type | Primary |
| End point timeframe: | |
| One Month post Dose 3, at Month 3 [PIII(M3)] | |

Notes:

[22] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 52 | 49 | |
| Units: Subjects | | | | |
| Haem, PIII(M3), Grade 3 | 0 | 0 | 0 | |
| WBC, PIII(M3) Grade 3 | 0 | 0 | 0 | |
| PLA, PIII(M3), Grade 3 | 0 | 0 | 0 | |
| ALA, PIII(M3), Grade 3 | 0 | 0 | 0 | |
| CREA PIII(M3), Grade 3 | 0 | 0 | 0 | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

| | |
|-----------------|---|
| End point title | Number of subjects with grade 3 haematological and biochemical levels ^[23] ^[24] |
|-----------------|---|

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA). Grade 3 = Haem.: < 5.0 g/dL; WBC.: 1.0 to 1.4 x 10³/μL; PLA.: < 25x10³/μL; ALA.: 5.1 to 10.0 x ULN and CREA: 3.1 to 6.0 x ULN.

| | |
|---|---------|
| End point type | Primary |
| End point timeframe: | |
| Six Months post Dose 1, at Month 6 [PI(M6)] | |

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 1 dose Group from the baseline period.

| | | | | |
|-----------------------------|-----------------------|--|--|--|
| End point values | SB692342 1 dose Group | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: Subjects | | | | |
| Haem, PI(M6), Grade 3 | 0 | | | |
| WBC, PI(M6) Grade 3 | 0 | | | |
| PLA, PI(M6), Grade 3 | 0 | | | |
| ALA, PI(M6), Grade 3 | 0 | | | |
| CREA PI(M6), Grade 3 | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

| | |
|-----------------|---|
| End point title | Number of subjects with grade 3 haematological and biochemical levels ^[25] ^[26] |
|-----------------|---|

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA). Grade 3 = Haem.: < 5.0 g/dL; WBC.: 1.0 to 1.4 x 10³/μL; PLA.: < 25x10³/μL; ALA.: 5.1 to 10.0 x ULN and CREA: 3.1 to 6.0 x ULN.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Six Months post Dose 2, at Month 7 [PII(M7)]

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group and the Control Menjugate Group from the baseline period.

| | | | | |
|-----------------------------|-----------------------|-------------------------|--|--|
| End point values | SB692342 2 dose Group | Control Menjugate Group | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 50 | 50 | | |
| Units: Subjects | | | | |
| Haem, PII(M7), Grade 3 | 0 | 0 | | |
| WBC, PII(M7) Grade 3 | 0 | 0 | | |
| PLA, PII(M7), Grade 3 | 0 | 0 | | |
| ALA, PII(M7), Grade 3 | 0 | 0 | | |
| CREA PII(M7), Grade 3 | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

| | |
|-----------------|---|
| End point title | Number of subjects with grade 3 haematological and biochemical levels ^{[27][28]} |
|-----------------|---|

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA). Grade 3 = Haem.: < 5.0 g/dL; WBC.: 1.0 to 1.4 x 10³/μL; PLA.: < 25x10³/μL; ALA.: 5.1 to 10.0 x ULN and CREA: 3.1 to 6.0 x ULN.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Six Months post Dose 3, at Month 13 [PIII(M13)]

Notes:

[27] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | Control Menjugate Group | | |
|-----------------------------|-----------------------|-------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 50 | 50 | | |
| Units: Subjects | | | | |
| Haem, PIII(M13), Grade 3 | 0 | 0 | | |
| WBC, PIII(M13) Grade 3 | 0 | 0 | | |
| PLA, PIII(M13), Grade 3 | 0 | 0 | | |
| ALA, PIII(M13), Grade 3 | 0 | 0 | | |
| CREA PIII(M13), Grade 3 | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

| | |
|-----------------|---|
| End point title | Number of subjects with grade 3 haematological and biochemical levels ^{[29][30]} |
|-----------------|---|

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA). Grade 3 = Haem.: < 5.0 g/dL; WBC.: 1.0 to 1.4 x 10³/μL; PLA.: < 25x10³/μL; ALA.: 5.1 to 10.0 x ULN and CREA: 3.1 to 6.0 x ULN.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Twelve Months post Dose 1, at Month 12 [PI(M12)]

Notes:

[29] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group from the baseline period.

| End point values | SB692342 2 dose Group | | | |
|-----------------------------|-----------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: Subjects | | | | |
| Haem, PI(M12), Grade 3 | 0 | | | |
| WBC, PI(M12) Grade 3 | 0 | | | |
| PLA, PI(M12), Grade 3 | 0 | | | |
| ALA, PI(M12), Grade 3 | 0 | | | |
| CREA PI(M12), Grade 3 | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

| | |
|-----------------|---|
| End point title | Number of subjects with grade 3 haematological and biochemical levels ^[31] ^[32] |
|-----------------|---|

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA). Grade 3 = Haem.: < 5.0 g/dL; WBC.: 1.0 to 1.4 x 10³/μL; PLA.: < 25x10³/μL; ALA.: 5.1 to 10.0 x ULN and CREA: 3.1 to 6.0 x ULN.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Twelve Months post Dose 2, at Month 13 [PII(M13)]

Notes:

[31] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | Control Menjugate Group | | |
|-----------------------------|-----------------------|-------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 50 | 50 | | |
| Units: Subjects | | | | |
| Haem, PII(M13), Grade 3 | 0 | 0 | | |

| | | | | |
|------------------------|---|---|--|--|
| WBC, PII(M13) Grade 3 | 0 | 0 | | |
| PLA, PII(M13), Grade 3 | 0 | 0 | | |
| ALA, PII(M13), Grade 3 | 0 | 0 | | |
| CREA PII(M13), Grade 3 | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

| | |
|-----------------|---|
| End point title | Number of subjects with grade 3 haematological and biochemical levels ^[33] |
|-----------------|---|

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA). Grade 3 = Haem.: < 5.0 g/dL; WBC.: 1.0 to 1.4 x 10³/μL; PLA.: < 25x10³/μL; ALA.: 5.1 to 10.0 x ULN and CREA: 3.1 to 6.0 x ULN.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Twelve Months post Dose 3, at Month 14 [PIII(M14)]

Notes:

[33] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 52 | 49 | |
| Units: Subjects | | | | |
| Haem, PIII(M14), Grade 3 | 0 | 0 | 0 | |
| WBC, PIII(M14) Grade 3 | 0 | 0 | 0 | |
| PLA, PIII(M14), Grade 3 | 0 | 0 | 1 | |
| ALA, PIII(M14), Grade 3 | 0 | 0 | 0 | |
| CREA PIII(M14), Grade 3 | 0 | 0 | 0 | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

| | |
|-----------------|---|
| End point title | Number of subjects with grade 3 haematological and biochemical levels ^[34] |
|-----------------|---|

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA). Grade 3 = Haem.: < 5.0 g/dL; WBC.: 1.0 to 1.4 x 10³/μL; PLA.: < 25x10³/μL; ALA.: 5.1 to 10.0 x ULN and CREA: 3.1 to 6.0 x ULN.

| | |
|--|---------|
| End point type | Primary |
| End point timeframe: | |
| Six Months post Dose 3, at Month 8 [PIII(M8)] | |
| Notes: | |
| [34] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. | |
| Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed. | |

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 50 | 49 | |
| Units: Subjects | | | | |
| Haem, PIII(M8), Grade 3 | 0 | 0 | 0 | |
| WBC, PIII(M8) Grade 3 | 0 | 0 | 0 | |
| PLA, PIII(M8), Grade 3 | 0 | 0 | 0 | |
| ALA, PIII(M8), Grade 3 | 0 | 1 | 0 | |
| CREA PIII(M8), Grade 3 | 0 | 0 | 0 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers

| | |
|--|---|
| End point title | Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers ^[35] |
| End point description: | |
| Immune markers expressed were among Interleukin-2 (IL-2), Interferon-gamma (INF-γ), Tumour necrosis factor-alpha (TNF-α) and CD40-ligand (CD40-L). | |
| End point type | Secondary |
| End point timeframe: | |
| Before vaccination (PRE) | |

Notes:

[35] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group |
|------------------------------|-----------------------|--|-----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 36 | 42 | 39 |
| Units: T cells/million cells | | | | |

| median (inter-quartile range (Q1-Q3)) | | | | |
|--|---------------|--------------------|-----------------|----------------|
| CD4 all doubles, PRE | 47 (23 to 87) | 59.5 (30.5 to 125) | 42.5 (22 to 71) | 88 (27 to 181) |
| CD4.CD40-L(+)+IL-2(+)+TNF- α (+)+INF- γ (+), PRE | 1 (1 to 1) | 1 (1 to 24.5) | 1 (1 to 12) | 14 (1 to 53) |
| CD4.CD40-L(+)+IL-2(+)+TNF- α (+)+INF- γ (-), PRE | 1 (1 to 12) | 1 (1 to 12) | 1 (1 to 1) | 1 (1 to 17) |
| CD4.CD40-L(+)+IL-2(+)+TNF- α (-)+INF- γ (+), PRE | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 13) |
| CD4.CD40-L(+)+IL-2(+)+TNF- α (-)+INF- γ (-), PRE | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD4.CD40-L(+)+IL-2(-)+TNF- α (+)+INF- γ (+), PRE | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD4.CD40-L(+)+IL-2(-)+TNF- α (+)+INF- γ (-), PRE | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD4.CD40-L(+)+IL-2(-)+TNF- α (-)+INF- γ (+), PRE | 1 (1 to 11) | 1 (1 to 13) | 1 (1 to 1) | 1 (1 to 15) |
| CD4.CD40-L(+)+IL-2(-)+TNF- α (-)+INF- γ (-), PRE | 14 (1 to 51) | 1 (1 to 28) | 11.5 (1 to 41) | 3 (1 to 62) |
| CD4.CD40-L(-)+IL-2(+)+TNF- α (+)+INF- γ (+), PRE | 1 (1 to 12) | 1 (1 to 24) | 1 (1 to 12) | 1 (1 to 27) |
| CD4.CD40-L(-)+IL-2(+)+TNF- α (+)+INF- γ (-), PRE | 1 (1 to 12) | 1 (1 to 6) | 1 (1 to 12) | 1 (1 to 1) |
| CD4.CD40-L(-)+IL-2(+)+TNF- α (-)+INF- γ (+), PRE | 1 (1 to 1) | 1 (1 to 11.5) | 1 (1 to 1) | 1 (1 to 20) |
| CD4.CD40-L(-)+IL-2(+)+TNF- α (-)+INF- γ (-), PRE | 1 (1 to 38) | 5.5 (1 to 29.5) | 1 (1 to 40) | 28 (1 to 63) |
| CD4.CD40-L(-)+IL-2(-)+TNF- α (+)+INF- γ (+), PRE | 1 (1 to 1) | 1 (1 to 12.5) | 1 (1 to 1) | 1 (1 to 1) |
| CD4.CD40-L(-)+IL-2(-)+TNF- α (+)+INF- γ (-), PRE | 1 (1 to 11) | 1 (1 to 27.5) | 1 (1 to 19) | 1 (1 to 11) |
| CD4.CD40-L(-)+IL-2(-)+TNF- α (-)+INF- γ (+), PRE | 1 (1 to 11) | 1 (1 to 21.5) | 1 (1 to 13) | 12 (1 to 47) |

| End point values | Control Menjugate Group | Control Tritanrix + Prevnar + Polio Sabin Group | | |
|--|-------------------------|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 34 | 39 | | |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD4 all doubles, PRE | 44.5 (11 to 65) | 52 (33 to 149) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF- α (+)+INF- γ (+), PRE | 1 (1 to 15) | 1 (1 to 30) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF- α (+)+INF- γ (-), PRE | 1 (1 to 1) | 1 (1 to 14) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF- α (-)+INF- γ (+), PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF- α (-)+INF- γ (-), PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF- α (+)+INF- γ (+), PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF- α (+)+INF- γ (-), PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF- α (-)+INF- γ (+), PRE | 1 (1 to 1) | 1 (1 to 13) | | |

| | | | | |
|--|---------------|--------------|--|--|
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), PRE | 1 (1 to 16) | 1 (1 to 52) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+), PRE | 1 (1 to 1) | 1 (1 to 27) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-), PRE | 1 (1 to 11) | 1 (1 to 16) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+), PRE | 1 (1 to 1) | 1 (1 to 15) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-), PRE | 1 (1 to 40) | 20 (1 to 62) | | |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), PRE | 1.5 (1 to 14) | 1 (1 to 21) | | |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+), PRE | 1 (1 to 22) | 15 (1 to 49) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers

| | |
|-----------------|---|
| End point title | Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers ^[36] |
|-----------------|---|

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Seven Days post each dose (D7)

Notes:

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Prevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group |
|---|-----------------------|---|-----------------------|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 42 | 43 | 43 |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD4 all doubles, D7 | 499 (250 to 1267) | 593.5 (269 to 1094) | 128 (83 to 379) | 174 (67 to 321) |
| CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), D7 | 24 (1 to 83) | 42.5 (14 to 66) | 1 (1 to 39) | 16 (1 to 43) |
| CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-), D7 | 47 (15 to 143) | 61.5 (18 to 157) | 12 (1 to 25) | 12 (1 to 29) |
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), D7 | 25 (1 to 103) | 19.5 (1 to 71) | 1 (1 to 26) | 13 (1 to 38) |

| | | | | |
|--|----------------------|----------------------|--------------------|---------------|
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+I INF-γ (-), D7 | 65 (12 to 286) | 82.5 (29 to 320) | 24 (1 to 52) | 14 (1 to 44) |
| CD4.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (+), D7 | 1 (1 to 15) | 1 (1 to 22) | 1 (1 to 1) | 1 (1 to 12) |
| CD4.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (-), D7 | 1 (1 to 32) | 11 (1 to 38) | 1 (1 to 11) | 1 (1 to 1) |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (+), D7 | 19 (9 to 61) | 36.5 (1 to 105) | 1 (1 to 19) | 13 (1 to 49) |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (-), D7 | 52 (1 to 144) | 112 (25 to 297) | 24 (1 to 102) | 21 (1 to 58) |
| CD4.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (+), D7 | 12 (1 to 32) | 14.5 (1 to 45) | 1 (1 to 24) | 1 (1 to 21) |
| CD4.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (-), D7 | 64 (12 to 107) | 35.5 (1 to 88) | 3 (1 to 24) | 1 (1 to 13) |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (+), D7 | 173 (38 to 232) | 102 (31 to 237) | 22 (1 to 86) | 22 (1 to 67) |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (-), D7 | 576 (245 to 1126) | 493 (309 to 960) | 138 (42 to 208) | 26 (1 to 134) |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+) +INF-γ(+), D7 | 1 (1 to 18) | 1 (1 to 36) | 1 (1 to 11) | 1 (1 to 13) |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+) +INF-γ (-), D7 | 25 (10 to 58) | 27.5 (5 to 85) | 1 (1 to 28) | 1 (1 to 20) |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF- γ(+), D7 | 232 (85 to 444) | 160.5 (61 to 314) | 30 (5 to 69) | 40 (12 to 91) |

| End point values | Control Menjugate Group | Control Tritanrix + Prevnar + Polio Sabin Group | | |
|--|-------------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 37 | 44 | | |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD4 all doubles, D7 | 55 (33 to 81) | 52.5 (33 to 85) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (+), D7 | 1 (1 to 15) | 1 (1 to 19) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (-), D7 | 1 (1 to 12) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-) +INF-γ (+), D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+I INF-γ (-), D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (+), D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (-), D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (+), D7 | 1 (1 to 1) | 1 (1 to 13) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (-), D7 | 9 (1 to 63) | 1 (1 to 37) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (+), D7 | 1 (1 to 12) | 11.5 (1 to 15.5) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (-), D7 | 1 (1 to 13) | 1 (1 to 7.5) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (+), D7 | 1 (1 to 1) | 1 (1 to 14.5) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (-), D7 | 1 (1 to 45) | 1 (1 to 42.5) | | |

| | | | | |
|---|--------------|----------------|--|--|
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), D7 | 11 (1 to 21) | 1 (1 to 13.5) | | |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+), D7 | 1 (1 to 17) | 14 (1 to 44.5) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers

| | |
|-----------------|---|
| End point title | Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers ^[37] |
|-----------------|---|

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

One Month post each dose (M1)

Notes:

[37] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group |
|---|-----------------------|--|-----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 41 | 43 | 44 | 41 |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD4 all doubles, M1 | 640 (403 to 1200) | 859 (348 to 1950) | 173.5 (93.5 to 476) | 235 (142 to 485) |
| CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M1 | 52 (1 to 157) | 50 (12 to 253) | 17 (1 to 63) | 25 (1 to 88) |
| CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-), M1 | 142 (48 to 300) | 195 (66 to 408) | 30 (11.5 to 82.5) | 56 (14 to 88) |
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), M1 | 14 (1 to 45) | 24 (1 to 132) | 1 (1 to 14) | 12 (1 to 26) |
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-), M1 | 109 (49 to 143) | 138 (56 to 327) | 27 (1 to 59) | 28 (12 to 63) |
| CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+), M1 | 1 (1 to 19) | 17 (1 to 37) | 1 (1 to 1) | 1 (1 to 12) |
| CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-), M1 | 15 (1 to 44) | 14 (1 to 63) | 1 (1 to 6) | 1 (1 to 1) |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+), M1 | 14 (1 to 41) | 24 (1 to 64) | 1 (1 to 12) | 12 (1 to 24) |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), M1 | 51 (1 to 107) | 51 (1 to 162) | 1 (1 to 50.5) | 16 (1 to 96) |

| | | | | |
|---|------------------|------------------|-----------------------|-----------------|
| CD4.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (+), M1 | 28 (1 to 109) | 20 (1 to 60) | 1 (1 to 45) | 12 (1 to 24) |
| CD4.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (-), M1 | 95 (32 to 251) | 127 (63 to 257) | 28 (1 to 59.5) | 15 (1 to 78) |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+), M1 | 57 (26 to 204) | 63 (27 to 118) | 19 (1 to 76) | 24 (1 to 44) |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-), M1 | 431 (239 to 838) | 449 (253 to 793) | 115.5 (42.5 to 277.5) | 127 (36 to 257) |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), M1 | 1 (1 to 27) | 1 (1 to 29) | 1 (1 to 7) | 1 (1 to 1) |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), M1 | 53 (5 to 106) | 51 (3 to 108) | 9.5 (1 to 38) | 19 (1 to 58) |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF- γ(+), M1 | 54 (18 to 107) | 71 (25 to 141) | 19.5 (1 to 49) | 11 (1 to 48) |

| End point values | Control Menjugate Group | Control Tritanrix + Prevnam + Polio Sabin Group | | |
|--|-------------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 34 | 42 | | |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD4 all doubles, M1 | 31 (22 to 66) | 55.5 (30 to 115) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (+), M1 | 1 (1 to 12) | 12 (1 to 26) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (-), M1 | 1 (1 to 12) | 1 (1 to 17) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), M1 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+I INF-γ (-), M1 | 1 (1 to 1) | 1 (1 to 12) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (+), M1 | 1 (1 to 1) | 1 (1 to 11) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (-), M1 | 1 (1 to 1) | 1 (1 to 12) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+), M1 | 1 (1 to 1) | 1 (1 to 14) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), M1 | 1 (1 to 42) | 1 (1 to 42) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (+), M1 | 1 (1 to 1) | 1 (1 to 15) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (-), M1 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+), M1 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-), M1 | 3 (1 to 33) | 23 (1 to 66) | | |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), M1 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), M1 | 1 (1 to 15) | 11 (1 to 35) | | |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF- γ(+), M1 | 1 (1 to 14) | 1 (1 to 21) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers

| | |
|-----------------|---|
| End point title | Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers ^[38] |
|-----------------|---|

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Six Months post each dose (M6)

Notes:

[38] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Prevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group |
|---|-----------------------|---|-----------------------|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 36 | 40 | 42 | 43 |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD4 all doubles, M6 | 633 (324 to 1062) | 512 (318.5 to 992.5) | 107.5 (47 to 184) | 107 (72 to 191) |
| CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M6 | 63 (18.5 to 129) | 65 (13 to 125) | 12 (1 to 28) | 16 (1 to 48) |
| CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-), M6 | 223 (78 to 403) | 202.5 (101.5 to 434) | 28 (1 to 50) | 17 (1 to 64) |
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), M6 | 18.5 (1 to 25.5) | 15.5 (1 to 29) | 1 (1 to 1) | 1 (1 to 13) |
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-), M6 | 68.5 (40.5 to 163) | 65 (34.5 to 184.5) | 1 (1 to 22) | 13 (1 to 41) |
| CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+), M6 | 1 (1 to 1) | 1 (1 to 13) | 1 (1 to 1) | 1 (1 to 1) |
| CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-), M6 | 12 (1 to 20.5) | 1 (1 to 26) | 1 (1 to 11) | 1 (1 to 1) |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+), M6 | 1 (1 to 6.5) | 1 (1 to 28) | 1 (1 to 1) | 1 (1 to 1) |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), M6 | 16.5 (1 to 71) | 40.5 (1 to 95.5) | 1 (1 to 28) | 2 (1 to 44) |
| CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+), M6 | 13.5 (1 to 59.5) | 13 (1 to 52.5) | 1 (1 to 14) | 1 (1 to 17) |

| | | | | |
|--|------------------------|-------------------------|----------------|--------------|
| CD4.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (-), M6 | 72 (38 to 206.5) | 86.5 (27 to 156.5) | 12 (1 to 28) | 5 (1 to 40) |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (+), M6 | 31 (1 to 84.5) | 26 (7 to 55) | 1 (1 to 13) | 1 (1 to 16) |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (-), M6 | 310.5 (60 to 591.5) | 171.5 (126.5 to 369) | 35.5 (1 to 68) | 48 (8 to 99) |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+) +INF-γ(+), M6 | 1 (1 to 18) | 1 (1 to 13) | 1 (1 to 1) | 1 (1 to 1) |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+) +INF-γ (-), M6 | 19 (1 to 71.5) | 27 (1 to 61) | 1 (1 to 12) | 1 (1 to 14) |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF- γ(+), M6 | 19.5 (1 to 58) | 14 (1 to 46.5) | 1 (1 to 14) | 1 (1 to 16) |

| End point values | Control Menjugate Group | Control Tritanrix + Prevnar + Polio Sabin Group | | |
|--|-------------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 34 | 44 | | |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD4 all doubles, M6 | 39 (23 to 71) | 41 (23 to 73.5) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (+), M6 | 1 (1 to 13) | 1 (1 to 13.5) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (-), M6 | 1 (1 to 15) | 1 (1 to 12.5) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-) +INF-γ (+), M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+I INF-γ (-), M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (+), M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (-), M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (+), M6 | 1 (1 to 11) | 1 (1 to 13) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (-), M6 | 1 (1 to 39) | 13.5 (1 to 48.5) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (+), M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (-), M6 | 1 (1 to 13) | 1 (1 to 1) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (+), M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (-), M6 | 10 (1 to 27) | 12.5 (1 to 41) | | |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+) +INF-γ(+), M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+) +INF-γ (-), M6 | 1 (1 to 14) | 1 (1 to 13.5) | | |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF- γ(+), M6 | 1 (1 to 18) | 1 (1 to 14) | | |

Statistical analyses

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers

| | |
|-----------------|---|
| End point title | Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers ^[39] |
|-----------------|---|

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Twelve Months post each dose (M12)

Notes:

[39] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Prevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group |
|--|-----------------------|---|-----------------------|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 38 | 41 | 45 | 41 |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD4 all doubles, M12 | 456.5 (237 to 1062) | 403 (245 to 745) | 104 (59 to 201) | 98 (52 to 157) |
| CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M12 | 51 (18 to 145) | 65 (18 to 99) | 16 (1 to 42) | 14 (1 to 48) |
| CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-), M12 | 176 (73 to 424) | 144 (80 to 329) | 28 (12 to 52) | 26 (13 to 47) |
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), M12 | 7 (1 to 39) | 13 (1 to 40) | 1 (1 to 1) | 1 (1 to 1) |
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-), M12 | 56.5 (24 to 145) | 67 (24 to 149) | 13 (1 to 21) | 1 (1 to 16) |
| CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+), M12 | 1 (1 to 13) | 1 (1 to 13) | 1 (1 to 1) | 1 (1 to 1) |
| CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-), M12 | 12.5 (1 to 37) | 1 (1 to 23) | 1 (1 to 1) | 1 (1 to 13) |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+), M12 | 1 (1 to 12) | 1 (1 to 17) | 1 (1 to 13) | 1 (1 to 1) |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), M12 | 10.5 (1 to 57) | 29 (1 to 81) | 1 (1 to 48) | 14 (1 to 67) |
| CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+), M12 | 13 (1 to 29) | 1 (1 to 17) | 1 (1 to 16) | 1 (1 to 1) |
| CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-), M12 | 60 (15 to 138) | 39 (13 to 91) | 12 (1 to 21) | 1 (1 to 12) |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+), M12 | 21 (1 to 56) | 19 (1 to 40) | 1 (1 to 12) | 1 (1 to 12) |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-), M12 | 179 (84 to 283) | 155 (74 to 300) | 30 (1 to 66) | 50 (22 to 87) |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), M12 | 1 (1 to 15) | 1 (1 to 12) | 1 (1 to 1) | 1 (1 to 1) |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), M12 | 3.5 (1 to 38) | 1 (1 to 35) | 3 (1 to 40) | 1 (1 to 39) |

| | | | | |
|---|----------------|-------------|-------------|-------------|
| CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+), M12 | 14.5 (1 to 49) | 2 (1 to 54) | 1 (1 to 25) | 1 (1 to 25) |
|---|----------------|-------------|-------------|-------------|

| End point values | Control Menjugate Group | Control Tritanrix + Prevnar + Polio Sabin Group | | |
|--|-------------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 33 | 43 | | |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD4 all doubles, M12 | 38 (22 to 61) | 41 (22 to 79) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M12 | 1 (1 to 1) | 1 (1 to 14) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-), M12 | 1 (1 to 14) | 1 (1 to 12) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-), M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+), M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-), M12 | 1 (1 to 1) | 1 (1 to 12) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+), M12 | 1 (1 to 12) | 1 (1 to 13) | | |
| CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), M12 | 22 (1 to 58) | 13 (1 to 72) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+), M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-), M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+), M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-), M12 | 1 (1 to 20) | 3 (1 to 25) | | |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), M12 | 1 (1 to 27) | 1 (1 to 19) | | |
| CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+), M12 | 1 (1 to 27) | 1 (1 to 41) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers

| | |
|-----------------|---|
| End point title | Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers ^[40] |
|-----------------|---|

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF- γ) and/or Tumour necrosis factor-alpha (TNF- α) and/or CD40-ligand (CD40-L).

End point type Secondary

End point timeframe:

Before vaccination (PRE)

Notes:

[40] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Prevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group |
|--|-----------------------|---|-----------------------|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 36 | 42 | 39 |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD8 all doubles, PRE | 11 (11 to 81) | 40.5 (11 to 70.5) | 11 (11 to 61) | 11 (11 to 93) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α (+)+INF- γ (+), PRE | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α (+)+INF- γ (-),PRE | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α (-)+INF- γ (+),PRE | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α (-)+INF- γ (-),PRE | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF- α (+)+INF- γ (+),PRE | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF- α (+)+INF- γ (-),PRE | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF- α (-)+INF- γ (+),PRE | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF- α (-)+INF- γ (-),PRE | 1 (1 to 44) | 1 (1 to 42) | 1 (1 to 53) | 1 (1 to 46) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α (+)+INF- γ (+),PRE | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α (+)+INF- γ (-),PRE | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α (-)+INF- γ (+),PRE | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α (-)+INF- γ (-),PRE | 8 (1 to 116) | 117 (40 to 260) | 57 (1 to 138) | 61 (1 to 166) |
| CD8.CD40-L(-)+IL-2(-)+TNF- α (+)+INF- γ (+),PRE | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(-)+TNF- α (+)+INF- γ (-),PRE | 1 (1 to 64) | 1 (1 to 14.5) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(-)+TNF- α (-)+INF- γ (+),PRE | 1 (1 to 40) | 1 (1 to 1) | 1 (1 to 23) | 1 (1 to 1) |

| End point values | Control Menjugate | Control Tritanrix + | | |
|------------------|-------------------|---------------------|--|--|
|------------------|-------------------|---------------------|--|--|

| | Group | Prevnar + Polio Sabin Group | | |
|--|-----------------|--------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 34 | 39 | | |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD8 all doubles, PRE | 11 (11 to 65) | 11 (11 to 47) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (+), PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (-),PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF-α (-) +INF-γ (+),PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+I NF-γ (-),PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (+),PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (-),PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (+),PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (-),PRE | 1 (1 to 50) | 1 (1 to 55) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (+),PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (-),PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (+),PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (-),PRE | 53.5 (1 to 91) | 65 (1 to 302) | | |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+),PRE | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-),PRE | 1 (1 to 28) | 1 (1 to 27) | | |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF- γ(+),PRE | 1 (1 to 2) | 1 (1 to 43) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers

| | |
|-----------------|---|
| End point title | Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers ^[41] |
|-----------------|---|

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Seven Days after each dose (D7)

Notes:

[41] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group |
|---|-----------------------|--|-----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 42 | 43 | 43 |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD8 all doubles, D7 | 61 (11 to 147) | 55 (11 to 161) | 43 (11 to 101) | 46 (11 to 82) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α (+)+INF- γ (+), D7 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α (+)+INF- γ (-),D7 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α (-)+INF- γ (+),D7 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α (-)+INF- γ (-),D7 | 1 (1 to 1) | 1 (1 to 31) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF- α (+)+INF- γ (+),D7 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF- α (+)+INF- γ (-),D7 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF- α (-)+INF- γ (+),D7 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF- α (-)+INF- γ (-),D7 | 34 (1 to 104) | 37 (1 to 119) | 6 (1 to 116) | 1 (1 to 100) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α (+)+INF- γ (+),D7 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α (+)+INF- γ (-),D7 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α (-)+INF- γ (+),D7 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α (-)+INF- γ (-),D7 | 61 (1 to 185) | 161.5 (1 to 574) | 1 (1 to 107) | 34 (1 to 303) |
| CD8.CD40-L(-)+IL-2(-)+TNF- α (+)+INF- γ (+),D7 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(-)+TNF- α (+)+INF- γ (-),D7 | 6 (1 to 64) | 7.5 (1 to 72) | 1 (1 to 67) | 1 (1 to 10) |
| CD8.CD40-L(-)+IL-2(-)+TNF- α (-)+INF- γ (+),D7 | 37 (1 to 89) | 1 (1 to 50) | 1 (1 to 70) | 1 (1 to 31) |

| End point values | Control Menjugate Group | Control Tritanrix + Pevnar + Polio Sabin Group | | |
|---------------------------------------|-------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 37 | 44 | | |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD8 all doubles, D7 | 11 (11 to 11) | 11 (11 to 28) | | |

| | | | | |
|---|-------------|---------------------|--|--|
| CD8.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (+), D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (-),D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF-α (-) +INF-γ (+),D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+I NF-γ (-),D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (+),D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (-),D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (+),D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (-),D7 | 3 (1 to 54) | 1 (1 to 25) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (+),D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (-),D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (+),D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (-),D7 | 1 (1 to 61) | 123 (1 to 289.5) | | |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+),D7 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-),D7 | 1 (1 to 85) | 1 (1 to 48) | | |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF- γ(+),D7 | 1 (1 to 30) | 1 (1 to 2.5) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers

| | |
|-----------------|---|
| End point title | Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers ^[42] |
|-----------------|---|

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

One Month after each dose (M1)

Notes:

[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group |
|---|-----------------------|--|-----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 41 | 43 | 44 | 41 |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD8 all doubles, M1 | 69 (11 to 145) | 82 (11 to 163) | 29.5 (11 to 80) | 81 (26 to 139) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α (+)+INF- γ (+), M1 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α (+)+INF- γ (-),M1 | 1 (1 to 1) | 1 (1 to 32) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α (-)+INF- γ (+),M1 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α (-)+INF- γ (-),M1 | 1 (1 to 1) | 1 (1 to 32) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF- α (+)+INF- γ (+),M1 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF- α (+)+INF- γ (-),M1 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF- α (-)+INF- γ (+),M1 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 56) |
| CD8.CD40-L(+)+IL-2(-)+TNF- α (-)+INF- γ (-),M1 | 1 (1 to 55) | 1 (1 to 46) | 1 (1 to 52) | 11 (1 to 99) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α (+)+INF- γ (+),M1 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α (+)+INF- γ (-),M1 | 1 (1 to 12) | 1 (1 to 28) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α (-)+INF- γ (+),M1 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α (-)+INF- γ (-),M1 | 1 (1 to 139) | 142 (1 to 308) | 2.5 (1 to 116) | 109 (2 to 218) |
| CD8.CD40-L(-)+IL-2(-)+TNF- α (+)+INF- γ (+),M1 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(-)+TNF- α (+)+INF- γ (-),M1 | 18 (1 to 87) | 12 (1 to 111) | 1 (1 to 50) | 1 (1 to 90) |
| CD8.CD40-L(-)+IL-2(-)+TNF- α (-)+INF- γ (+),M1 | 1 (1 to 65) | 1 (1 to 65) | 1 (1 to 5.5) | 1 (1 to 64) |

| End point values | Control Menjugate Group | Control Tritanrix + Pevnar + Polio Sabin Group | | |
|---|-------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 34 | 42 | | |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD8 all doubles, M1 | 11 (11 to 28) | 11 (11 to 53) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF- α (+)+INF- γ (+), M1 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF- α (+)+INF- γ (-),M1 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF- α (-)+INF- γ (+),M1 | 1 (1 to 1) | 1 (1 to 1) | | |

| | | | | |
|---|---------------|---------------|--|--|
| CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+I INF-γ (-),M1 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (+),M1 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (-),M1 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (+),M1 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (-),M1 | 2.5 (1 to 85) | 4 (1 to 109) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (+),M1 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (-),M1 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (+),M1 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (-),M1 | 1 (1 to 48) | 86 (1 to 330) | | |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (+) +INF-γ(+),M1 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (+) +INF-γ (-),M1 | 1 (1 to 51) | 1 (1 to 35) | | |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF- γ(+),M1 | 1 (1 to 5) | 1 (1 to 1) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers

| | |
|-----------------|---|
| End point title | Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers ^[43] |
|-----------------|---|

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Six Months after each dose (M6)

Notes:

[43] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group |
|---------------------------------------|-----------------------|--|-----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 36 | 40 | 42 | 43 |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |

| | | | | |
|---|---------------|----------------|---------------|---------------|
| CD8 all doubles, M6 | 11 (11 to 53) | 11 (11 to 20) | 11 (11 to 32) | 11 (11 to 11) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (+), M6 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (-),M6 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(+)+TNF-α (-) +INF-γ (+),M6 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+I INF-γ (-),M6 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (+),M6 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (-),M6 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (+),M6 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (-),M6 | 1 (1 to 25.5) | 2 (1 to 65) | 1 (1 to 44) | 1 (1 to 63) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (+),M6 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (-),M6 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (+),M6 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (-),M6 | 1 (1 to 29.5) | 27.5 (1 to 60) | 38 (1 to 91) | 1 (1 to 56) |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+),M6 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-),M6 | 1 (1 to 54.5) | 1 (1 to 55.5) | 1 (1 to 3) | 1 (1 to 60) |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF- γ(+),M6 | 1 (1 to 33) | 1 (1 to 36.5) | 1 (1 to 1) | 1 (1 to 40) |

| End point values | Control Menjugate Group | Control Tritanrix + Prevnar + Polio Sabin Group | | |
|---|-------------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 34 | 44 | | |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD8 all doubles, M6 | 11 (11 to 29) | 11 (11 to 11) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (+), M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (-),M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF-α (-) +INF-γ (+),M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+I INF-γ (-),M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (+),M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (-),M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (+),M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (-),M6 | 1 (1 to 52) | 2 (1 to 59) | | |

| | | | | |
|---|--------------|---------------|--|--|
| CD8.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (+),M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (-),M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (+),M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (-),M6 | 28 (1 to 67) | 1 (1 to 43.5) | | |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (+) +INF-γ (+),M6 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (+) +INF-γ (-),M6 | 1 (1 to 36) | 1 (1 to 49) | | |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF- γ(+),M6 | 1 (1 to 1) | 1 (1 to 1) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers

| | |
|-----------------|---|
| End point title | Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers ^[44] |
|-----------------|---|

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Twelve Months after each dose (M12)

Notes:

[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group |
|--|--------------------------|--|--------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 38 | 41 | 45 | 41 |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD8 all doubles, M12 | 11 (11 to 52) | 11 (11 to 35) | 11 (11 to 38) | 11 (11 to 41) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (+), M12 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (-),M12 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(+)+TNF-α (-) +INF-γ (+),M12 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+I INF-γ (-),M12 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |

| | | | | |
|--|----------------|--------------|-------------|--------------|
| CD8.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (+),M12 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (-),M12 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (+),M12 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (-),M12 | 1 (1 to 29) | 1 (1 to 64) | 1 (1 to 68) | 1 (1 to 35) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (+),M12 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (-),M12 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (+),M12 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (-),M12 | 14.5 (1 to 92) | 16 (1 to 77) | 1 (1 to 59) | 1 (1 to 35) |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (+) +INF-γ(+),M12 | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) | 1 (1 to 1) |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (+) +INF-γ (-),M12 | 1 (1 to 34) | 1 (1 to 50) | 1 (1 to 58) | 1 (1 to 65) |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF- γ(+),M12 | 1.5 (1 to 67) | 1 (1 to 48) | 1 (1 to 25) | 1 (1 to 128) |

| End point values | Control Menjugate Group | Control Tritanrix + Prevnar + Polio Sabin Group | | |
|--|-------------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 33 | 43 | | |
| Units: T cells/million cells | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| CD8 all doubles, M12 | 11 (11 to 41) | 11 (11 to 42) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (+), M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF- α(+)+INF-γ (-),M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF-α (-) +INF-γ (+),M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+I INF-γ (-),M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (+),M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF- α(+)+INF-γ (-),M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (+),M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(+)+IL-2(-)+TNF-α (-) +INF-γ (-),M12 | 1 (1 to 32) | 1 (1 to 40) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (+),M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF- α(+)+INF-γ (-),M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (+),M12 | 1 (1 to 1) | 1 (1 to 1) | | |
| CD8.CD40-L(-)+IL-2(+)+TNF-α (-) +INF-γ (-),M12 | 1 (1 to 57) | 15 (1 to 66) | | |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (+) +INF-γ(+),M12 | 1 (1 to 5) | 1 (1 to 1) | | |

| | | | | |
|---|--------------|-------------|--|--|
| CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-),M12 | 1 (1 to 117) | 1 (1 to 22) | | |
| CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+),M12 | 11 (1 to 57) | 1 (1 to 33) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects against M72 antigen

| | |
|--|---|
| End point title | Number of seropositive subjects against M72 antigen ^[45] |
| End point description: A seropositive subject was a subject whose M72 antibody concentration was greater than or equal to 2.8 ELISA units per millilitre (EL.U/mL). | |
| End point type | Secondary |
| End point timeframe: Before vaccination (PRE) and after each dose [at 1, 6 and 12 months post-vaccination (M1, M6 and M12)] | |

Notes:

[45] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group |
|-------------------------------------|-----------------------|--|-----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 43 | 44 | 48 | 46 |
| Units: Subjects | | | | |
| Anti-M72, PRE (N=43;44;48;46;39;46) | 0 | 0 | 0 | 0 |
| Anti-M72, M1 (N=42;43;45;44;34;43) | 42 | 43 | 39 | 39 |
| Anti-M72, M6 (N=40;41;45;45;36;45) | 40 | 41 | 32 | 35 |
| Anti-M72, M12 (N=41;42;47;45;35;43) | 41 | 42 | 35 | 31 |

| End point values | Control Menjugate Group | Control Tritanrix + Pevnar + Polio Sabin Group | | |
|-------------------------------------|-------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 39 | 46 | | |
| Units: Subjects | | | | |
| Anti-M72, PRE (N=43;44;48;46;39;46) | 1 | 0 | | |
| Anti-M72, M1 (N=42;43;45;44;34;43) | 1 | 0 | | |
| Anti-M72, M6 (N=40;41;45;45;36;45) | 0 | 1 | | |
| Anti-M72, M12 (N=41;42;47;45;35;43) | 1 | 2 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration of antibodies against M72 antigen

| | |
|-----------------|---|
| End point title | Concentration of antibodies against M72 antigen ^[46] |
|-----------------|---|

End point description:

Concentrations given in EL.U/mL were expressed as Geometric Mean Concentrations (GMCs).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before vaccination (PRE) and after each dose [at 1, 6 and 12 months post-vaccination (M1, M6 and M12)]

Notes:

[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Prevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group |
|--|--------------------------|---|-----------------------|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 43 | 44 | 48 | 46 |
| Units: EL.U/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-M72, PRE (N=43;44;48;46;39;46) | 1.4 (1.4 to 1.4) | 1.4 (1.4 to 1.4) | 1.4 (1.4 to 1.4) | 1.4 (1.4 to 1.4) |
| Anti-M72, M1 (N=42;43;45;44;34;43) | 1275.2 (981.3 to 1657.2) | 1264 (928 to 1721.5) | 8 (6 to 10.7) | 7.4 (5.3 to 10.2) |
| Anti-M72, M6 (N=40;41;45;45;36;45) | 98.9 (75.2 to 130.1) | 102.6 (78.7 to 133.9) | 4.6 (3.4 to 6.2) | 4.9 (3.8 to 6.4) |
| Anti-M72, M12 (N=41;42;47;45;35;43) | 68.3 (50.7 to 92) | 76 (56.6 to 102) | 5.3 (3.9 to 7) | 4.3 (3.2 to 5.8) |

| End point values | Control Menjugate Group | Control Tritanrix + Prevnar + Polio Sabin Group | | |
|-------------------------------------|-------------------------|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 39 | 46 | | |
| Units: EL.U/mL | | | | |
| geometric mean (confidence interval | | | | |

| | | | | |
|-------------------------------------|------------------|------------------|--|--|
| 95%) | | | | |
| Anti-M72, PRE (N=43;44;48;46;39;46) | 1.5 (1.3 to 1.7) | 1.4 (1.4 to 1.4) | | |
| Anti-M72, M1 (N=42;43;45;44;34;43) | 1.5 (1.3 to 1.7) | 1.4 (1.4 to 1.4) | | |
| Anti-M72, M6 (N=40;41;45;45;36;45) | 1.4 (1.4 to 1.4) | 1.4 (1.4 to 1.5) | | |
| Anti-M72, M12 (N=41;42;47;45;35;43) | 1.4 (1.4 to 1.5) | 1.5 (1.4 to 1.7) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against diphtheria toxoid (Anti-D) and tetanus toxoid (Anti-T)

| | |
|-----------------|---|
| End point title | Number of seroprotected subjects against diphtheria toxoid (Anti-D) and tetanus toxoid (Anti-T) |
|-----------------|---|

End point description:

A seroprotected subject was a subject whose anti-diphtheria toxoid (anti-D)/anti-tetanus toxoid (anti-T) antibody concentration was greater than or equal to (\geq) 0.1 international-units per millilitre (IU/mL).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

| End point values | SB692392 2 dose + Tritanrix + Prevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group | Control Tritanrix + Prevnar + Polio Sabin Group | |
|------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 43 | 43 | 43 | |
| Units: Subjects | | | | |
| Anti-D, PRE (N=37,38,38) | 6 | 10 | 6 | |
| Anti-D,PIII(M3) (N=43,43,43) | 43 | 43 | 43 | |
| Anti-T, PRE(N=37,38,38) | 32 | 35 | 35 | |
| Anti-T,PIII(M3) (N=43,43,43) | 43 | 43 | 43 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-D, Anti-T antibody concentrations

| | |
|-----------------|--|
| End point title | Anti-D, Anti-T antibody concentrations |
|-----------------|--|

End point description:

Concentrations given in IU/mL, were expressed as Geometric Mean Concentrations (GMCs).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|--|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 43 | 43 | 43 | |
| Units: IU/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-D, PRE (N=37,38,38) | 0.1 (0.1 to 0.1) | 0.1 (0.1 to 0.1) | 0.1 (0.1 to 0.1) | |
| Anti-D,PIII(M3) (N=43,43,43) | 2.1 (1.6 to 2.7) | 2.4 (1.8 to 3.1) | 2.5 (2 to 3.1) | |
| Anti-T, PRE(N=37,38,38) | 0.6 (0.4 to 1) | 1 (0.6 to 1.5) | 1 (0.6 to 1.6) | |
| Anti-T,PIII(M3) (N=43,43,43) | 5.5 (4.3 to 7.1) | 4.8 (3.6 to 6.4) | 6.3 (4.8 to 8.3) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against Haemophilus influenza Type B (Anti-PRP)

| | |
|-----------------|--|
| End point title | Number of seroprotected subjects against Haemophilus influenza Type B (Anti-PRP) |
|-----------------|--|

End point description:

A seroprotected subject was a subject whose anti-PRP antibody concentration was ≥ 0.15 micrograms per millilitre ($\mu\text{g/mL}$).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|--------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 47 | 46 | 48 | |
| Units: Subjects | | | | |
| Anti-PRP, PRE (N=47,46,48) | 8 | 14 | 12 | |
| Anti-PRP,PIII(M3) (N=44,44,43) | 44 | 44 | 43 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PRP antibody concentrations

| | |
|-----------------|----------------------------------|
| End point title | Anti-PRP antibody concentrations |
|-----------------|----------------------------------|

End point description:

Concentrations given in µg/mL were expressed as Geometric Mean Concentrations (GMCs).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|--|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 47 | 46 | 48 | |
| Units: µg/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-PRP, PRE (N=47,46,48) | 0.1 (0.1 to 0.1) | 0.1 (0.1 to 0.2) | 0.1 (0.1 to 0.2) | |
| Anti-PRP,PIII(M3) (N=44,44,43) | 28.2 (20.3 to 39.1) | 30.3 (21.8 to 42.1) | 31.2 (21.8 to 44.7) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects against Bordetella Pertussis (Anti-BPT)

| | |
|-----------------|---|
| End point title | Number of seropositive subjects against Bordetella Pertussis (Anti-BPT) |
|-----------------|---|

End point description:

A seropositive subject was a subject whose anti-BPT antibody concentration was ≥ 15 EL.U/mL.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

| End point values | SB692392 2 dose + Tritanrix + Prevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group | Control Tritanrix + Prevnar + Polio Sabin Group | |
|--------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 44 | 43 | 43 | |
| Units: Subjects | | | | |
| Anti-BPT, PRE (N=41,40,43) | 1 | 1 | 1 | |
| Anti-BPT,PIII(M3) (N=44,43,43) | 44 | 43 | 43 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-BPT antibody concentrations

| | |
|---|----------------------------------|
| End point title | Anti-BPT antibody concentrations |
| End point description: Concentrations given in EL.U/mL were expressed as Geometric Mean Concentrations (GMCs). | |
| End point type | Secondary |
| End point timeframe: Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)] | |

| End point values | SB692392 2 dose + Tritanrix + Prevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group | Control Tritanrix + Prevnar + Polio Sabin Group | |
|--|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 44 | 43 | 43 | |
| Units: EL.U/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-BPT, PRE (N=41,40,43) | 7.7 (7.3 to 8) | 7.6 (7.4 to 7.9) | 7.6 (7.4 to 7.9) | |
| Anti-BPT,PIII(M3) (N=44,43,43) | 139.4 (117.7 to 164.9) | 132.1 (116.6 to 149.5) | 131.5 (113.5 to 152.5) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects against Hepatitis B (Anti-HB)

| | |
|--|---|
| End point title | Number of seropositive subjects against Hepatitis B (Anti-HB) |
| End point description: A seropositive subject was a subject whose anti-HB antibody concentration was ≥ 10 milli-international units per millilitre (mIU/mL). | |

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)] | |

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|--------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 44 | 44 | 43 | |
| Units: Subjects | | | | |
| Anti-HB, PRE (N=41,40,41) | 9 | 14 | 13 | |
| Anti-HB, PIII(M3) (N=44,44,43) | 42 | 43 | 42 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects against Hepatitis B (Anti-HB) with antibody concentrations ≥ 100 mIU/mL

| | |
|-----------------|--|
| End point title | Number of seropositive subjects against Hepatitis B (Anti-HB) with antibody concentrations ≥ 100 mIU/mL |
|-----------------|--|

End point description:

A decrease in the specificity of the anti-HB ELISA assay had been observed in some studies for low levels of antibody (10-100 mIU/mL). The table shows updated results following partial or complete retesting/reanalysis. Following from this, the table shows data with titers ≥ 100 mIU/mL.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)] | |

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|-------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 44 | 44 | 43 | |
| Units: Subjects | | | | |
| Anti-HB, PRE (N=41,40,41) | 2 | 2 | 2 | |
| Anti-HB,PIII(M3) (N=44,44,43) | 42 | 42 | 42 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-HB antibody concentrations

| | |
|-----------------|---------------------------------|
| End point title | Anti-HB antibody concentrations |
|-----------------|---------------------------------|

End point description:

Concentrations given in mIU/mL were expressed as Geometric Mean Concentrations (GMCs).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|--|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 44 | 44 | 43 | |
| Units: mIU/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-HB, PRE (N=41,40,41) | 8.3 (6 to 11.4) | 10 (7.1 to 14) | 9 (6.7 to 12.2) | |
| Anti-HB,PIII(M3) (N=44,44,43) | 1725.5 (1045 to 2849) | 1471.8 (947.5 to 2286) | 2153 (1468.2 to 3157.4) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects against Polio (Anti-Polio1, Anti-Polio2, Anti-Polio3)

| | |
|-----------------|---|
| End point title | Number of seropositive subjects against Polio (Anti-Polio1, Anti-Polio2, Anti-Polio3) |
|-----------------|---|

End point description:

A seropositive subject was a subject whose anti-polio antibody titer was $\geq 1:8$.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|------------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 46 | 45 | 48 | |
| Units: Subjects | | | | |
| Anti-Polio1, PRE (N=46,45,48) | 36 | 38 | 39 | |
| Anti-Polio1, PIII(M3) (N=44,44,43) | 41 | 43 | 42 | |
| Anti-Polio2,PRE (N=46,45,48) | 33 | 32 | 38 | |
| Anti-Polio2,PIII(M3) (N=44,44,43) | 43 | 42 | 42 | |
| Anti-Polio3,PRE (N=46,45,48) | 21 | 18 | 14 | |
| Anti-Polio3,PIII(M3) (N=44,44,43) | 42 | 38 | 39 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-Polio1, Anti-Polio2, Anti-Polio3 antibody titers

| | |
|--|---|
| End point title | Anti-Polio1, Anti-Polio2, Anti-Polio3 antibody titers |
| End point description: Concentrations given in titers were expressed as Geometric Mean Titers (GMTs). | |
| End point type | Secondary |
| End point timeframe: Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)] | |

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|--|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 46 | 45 | 48 | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-Polio1, PRE (N=46,45,48) | 56.3 (30.7 to 103.2) | 48.8 (27.3 to 87.5) | 103.8 (58.1 to 185.3) | |
| Anti-Polio1, PIII(M3) (N=44,44,43) | 299.9 (167.6 to 536.7) | 397.8 (240.2 to 658.8) | 573.1 (368.7 to 890.6) | |
| Anti-Polio2,PRE (N=46,45,48) | 51.8 (28.8 to 93.2) | 53.2 (28 to 101) | 61.2 (34.8 to 107.8) | |
| Anti-Polio2,PIII(M3) (N=44,44,43) | 458.7 (307.7 to 683.7) | 524.3 (331.1 to 830.3) | 499.9 (317.7 to 786.5) | |
| Anti-Polio3,PRE (N=46,45,48) | 15.2 (9 to 25.6) | 15.4 (8.6 to 27.6) | 10.9 (6.7 to 17.9) | |
| Anti-Polio3,PIII(M3) (N=44,44,43) | 154.8 (100.8 to 237.8) | 103.5 (59.7 to 179.6) | 123 (73.6 to 205.8) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects against Streptococcus pneumoniae (Anti-4, Anti-6B, Anti-9V, Anti-14, Anti-18C, Anti-19F, Anti-23F)

| | |
|-----------------|--|
| End point title | Number of seropositive subjects against Streptococcus pneumoniae (Anti-4, Anti-6B, Anti-9V, Anti-14, Anti-18C, Anti-19F, Anti-23F) |
|-----------------|--|

End point description:

A seropositive subject was a subject whose anti-S pneumoniae antibody concentration was ≥ 0.05 $\mu\text{g/mL}$.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

| End point values | SB692392 2 dose + Tritanrix + Prevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group | Control Tritanrix + Prevnar + Polio Sabin Group | |
|---------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 44 | 44 | 43 | |
| Units: Subjects | | | | |
| Anti-4, PRE (N=39,39,40) | 18 | 21 | 12 | |
| Anti-4, PIII(M3) (N=43,43,43) | 43 | 43 | 43 | |
| Anti-6B,PRE (N=38,39,40) | 29 | 27 | 26 | |
| Anti-6B,PIII(M3) (N=44,43,43) | 44 | 41 | 40 | |
| Anti-9V,PRE (N=37,39,39) | 28 | 33 | 25 | |
| Anti-9V,PIII(M3) (N=43,43,43) | 43 | 43 | 43 | |
| Anti-14,PRE (N=39,38,40) | 39 | 38 | 38 | |
| Anti-14,PIII(M3) (N=44,44,43) | 44 | 44 | 43 | |
| Anti-18C, PRE (N=42,40,42) | 30 | 35 | 26 | |
| Anti-18C, PIII(M3) (N=43,44,43) | 43 | 44 | 43 | |
| Anti-19F, PRE (N=37,38,40) | 35 | 37 | 39 | |
| Anti-19F, PIII(M3) (N=44,44,43) | 44 | 44 | 43 | |
| Anti-23F,PRE (N=41,40,42) | 25 | 30 | 26 | |
| Anti-23F, PIII(M3) (N=44,43,43) | 43 | 43 | 42 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with *S. pneumoniae* antibody concentrations ≥ 0.2 $\mu\text{g/mL}$

| | |
|-----------------|--|
| End point title | Number of subjects with <i>S. pneumoniae</i> antibody concentrations ≥ 0.2 $\mu\text{g/mL}$ |
|-----------------|--|

End point description:

A seroconverted subject is a vaccinated subject with at least a four fold increased antibody titer post vaccination.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|---------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 44 | 44 | 43 | |
| Units: Subjects | | | | |
| Anti-4, PRE (N=39,39,40) | 5 | 10 | 2 | |
| Anti-4, PIII(M3) (N=43,43,43) | 43 | 43 | 43 | |
| Anti-6B,PRE (N=38,39,40) | 8 | 5 | 6 | |
| Anti-6B,PIII(M3) (N=44,43,43) | 38 | 40 | 35 | |
| Anti-9V,PRE (N=37,39,39) | 18 | 20 | 10 | |
| Anti-9V,PIII(M3) (N=43,43,43) | 43 | 43 | 43 | |
| Anti-14,PRE (N=39,38,40) | 34 | 33 | 33 | |
| Anti-14,PIII(M3) (N=44,44,43) | 44 | 43 | 43 | |
| Anti-18C, PRE (N=42,40,42) | 10 | 17 | 9 | |
| Anti-18C, PIII(M3) (N=43,44,43) | 43 | 43 | 42 | |
| Anti-19F, PRE (N=37,38,40) | 30 | 30 | 26 | |
| Anti-19F, PIII(M3) (N=44,44,43) | 43 | 44 | 43 | |
| Anti-23F,PRE (N=41,40,42) | 9 | 11 | 14 | |
| Anti-23F, PIII(M3) (N=44,43,43) | 42 | 41 | 42 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-4, Anti-6B, Anti-9V, Anti-14, Anti-18C, Anti-19F, Anti-23F antibody concentrations

| | |
|-----------------|---|
| End point title | Anti-4, Anti-6B, Anti-9V, Anti-14, Anti-18C, Anti-19F, Anti-23F antibody concentrations |
|-----------------|---|

End point description:

Concentrations, given in $\mu\text{g/mL}$, were expressed as Geometric Mean Concentrations (GMCs).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|--|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 44 | 44 | 43 | |
| Units: µg/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-4, PRE (N=39,39,40) | 0.1 (0 to 0.1) | 0.1 (0.1 to 0.1) | 0 (0 to 0) | |
| Anti-4, PIII(M3) (N=43,43,43) | 7.7 (6.2 to 9.7) | 6.4 (5.3 to 7.8) | 8.1 (6.5 to 10) | |
| Anti-6B,PRE (N=38,39,40) | 0.1 (0.1 to 0.1) | 0.1 (0.1 to 0.1) | 0.1 (0.1 to 0.1) | |
| Anti-6B,PIII(M3) (N=44,43,43) | 2.3 (1.4 to 3.8) | 1.5 (0.9 to 2.4) | 1.5 (0.8 to 2.7) | |
| Anti-9V,PRE (N=37,39,39) | 0.1 (0.1 to 0.1) | 0.2 (0.1 to 0.3) | 0.1 (0.1 to 0.1) | |
| Anti-9V,PIII(M3) (N=43,43,43) | 5.8 (4.4 to 7.7) | 4.1 (3 to 5.6) | 6 (4.5 to 8.1) | |
| Anti-14,PRE (N=39,38,40) | 0.8 (0.6 to 1.2) | 1.1 (0.7 to 1.6) | 0.7 (0.4 to 1) | |
| Anti-14,PIII(M3) (N=44,44,43) | 3.6 (2.5 to 5.3) | 3.3 (2.3 to 4.7) | 4.2 (2.8 to 6.2) | |
| Anti-18C, PRE (N=42,40,42) | 0.1 (0.1 to 0.1) | 0.2 (0.1 to 0.2) | 0.1 (0.1 to 0.1) | |
| Anti-18C, PIII(M3) (N=43,44,43) | 7.2 (5.7 to 9) | 5.1 (3.8 to 7) | 6.1 (4.2 to 8.8) | |
| Anti-19F, PRE (N=37,38,40) | 0.4 (0.3 to 0.6) | 0.5 (0.3 to 0.7) | 0.3 (0.2 to 0.5) | |
| Anti-19F, PIII(M3) (N=44,44,43) | 5.8 (4.1 to 8.2) | 5.4 (4.2 to 6.9) | 5.9 (4.5 to 7.5) | |
| Anti-23F,PRE (N=41,40,42) | 0.1 (0.1 to 0.1) | 0.1 (0.1 to 0.1) | 0.1 (0.1 to 0.1) | |
| Anti-23F, PIII(M3) (N=44,43,43) | 3.2 (2.1 to 4.8) | 3 (2 to 4.6) | 3.8 (2.5 to 5.7) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events (SAEs)

| | |
|-----------------|---|
| End point title | Number of subjects with serious adverse events (SAEs) ^[47] |
|-----------------|---|

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life-threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From Day 0 up to 12 months post last vaccination

Notes:

[47] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group |
|-----------------------------|-----------------------|--|-----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 50 | 49 | 50 | 52 |
| Units: Subjects | | | | |
| Any SAEs | 2 | 1 | 3 | 1 |

| End point values | Control Menjugate Group | Control Tritanrix + Pevnar + Polio Sabin Group | | |
|-----------------------------|-------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 50 | 49 | | |
| Units: Subjects | | | | |
| Any SAEs | 3 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Normal, grade 1 (G1), grade 2 (G2) or grade 4 (G4) Haematological and Biochemical Markers

| | |
|-----------------|---|
| End point title | Number of Subjects with Normal, grade 1 (G1), grade 2 (G2) or grade 4 (G4) Haematological and Biochemical Markers ^[48] |
|-----------------|---|

End point description:

Levels assessed for Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA) were: normal, G1, G2 and G4 . Values that did not fall under normal levels or assessed grades were missing.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before vaccination (PRE)

Notes:

[48] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692342 1 dose Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group |
|-----------------------------|-----------------------|--|-----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 50 | 49 | 50 | 52 |
| Units: Subjects | | | | |
| Haem, PRE, Normal | 49 | 48 | 50 | 51 |
| Haem, PRE, G1 | 0 | 1 | 0 | 0 |

| | | | | |
|--------------------|----|----|----|----|
| Haem, PRE, G2 | 1 | 0 | 0 | 1 |
| Haem, PRE, G4 | 0 | 0 | 0 | 0 |
| WBC, PRE, Normal | 45 | 48 | 49 | 52 |
| WBC, PRE, G1 | 0 | 0 | 0 | 0 |
| WBC, PRE, G2 | 0 | 0 | 0 | 0 |
| WBC, PRE, G4 | 0 | 0 | 0 | 0 |
| PLA, PRE, Normal | 48 | 49 | 49 | 52 |
| PLA, PRE, G1 | 2 | 0 | 0 | 0 |
| PLA, PRE, G2 | 0 | 0 | 0 | 0 |
| PLA, PRE, G4 | 0 | 0 | 0 | 0 |
| ALA, PRE, Normal | 42 | 47 | 39 | 51 |
| ALA, PRE, G1 | 0 | 1 | 0 | 0 |
| ALA, PRE, G2 | 0 | 0 | 0 | 0 |
| ALA, PRE, G4 | 0 | 0 | 0 | 0 |
| CREA PRE, Normal | 42 | 48 | 39 | 51 |
| CREA PRE, G1 | 0 | 0 | 0 | 0 |
| CREA PRE, G2 | 0 | 0 | 0 | 0 |
| CREA PRE, G4 | 0 | 0 | 0 | 0 |
| Haem, PRE, Missing | 0 | 0 | 0 | 0 |
| WBC, PRE, Missing | 5 | 1 | 1 | 0 |
| PLA, PRE, Missing | 0 | 0 | 0 | 0 |
| ALA, PRE, Missing | 8 | 1 | 11 | 1 |
| CREA, PRE, Missing | 8 | 1 | 11 | 1 |

| End point values | Control Menjugate Group | Control Tritanrix + Prevnar + Polio Sabin Group | | |
|-----------------------------|-------------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 50 | 49 | | |
| Units: Subjects | | | | |
| Haem, PRE, Normal | 48 | 49 | | |
| Haem, PRE, G1 | 1 | 0 | | |
| Haem, PRE, G2 | 0 | 0 | | |
| Haem, PRE, G4 | 0 | 0 | | |
| WBC, PRE, Normal | 43 | 47 | | |
| WBC, PRE, G1 | 0 | 0 | | |
| WBC, PRE, G2 | 0 | 0 | | |
| WBC, PRE, G4 | 0 | 0 | | |
| PLA, PRE, Normal | 48 | 49 | | |
| PLA, PRE, G1 | 1 | 0 | | |
| PLA, PRE, G2 | 0 | 0 | | |
| PLA, PRE, G4 | 0 | 0 | | |
| ALA, PRE, Normal | 40 | 48 | | |
| ALA, PRE, G1 | 0 | 1 | | |
| ALA, PRE, G2 | 1 | 0 | | |
| ALA, PRE, G4 | 0 | 0 | | |
| CREA PRE, Normal | 41 | 49 | | |
| CREA PRE, G1 | 0 | 0 | | |
| CREA PRE, G2 | 0 | 0 | | |

| | | | | |
|--------------------|---|---|--|--|
| CREA, PRE, G4 | 0 | 0 | | |
| Haem, PRE, Missing | 1 | 0 | | |
| WBC, PRE, Missing | 7 | 2 | | |
| PLA, PRE, Missing | 1 | 0 | | |
| ALA, PRE, Missing | 9 | 0 | | |
| CREA, PRE, Missing | 9 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers

| | |
|-----------------|--|
| End point title | Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers ^[49] |
|-----------------|--|

End point description:

Levels assessed for Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA) were : normal, grade 1 (G1), grade 2 (G2) and grade 4 (G4). Values that did not fall under normal levels or assessed grades were missing.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Seven days post Dose 1 [PI(D7)]

Notes:

[49] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692342 1 dose Group | Control Menjugate Group | |
|-----------------------------|-----------------------|-----------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 50 | 50 | 50 | |
| Units: Subjects | | | | |
| Haem, PI(D7), Normal | 49 | 48 | 48 | |
| Haem, PI(D7), G1 | 0 | 0 | 0 | |
| Haem, PI(D7), G2 | 0 | 0 | 0 | |
| Haem, PI(D7), G4 | 0 | 0 | 0 | |
| WBC, PI(D7), Normal | 46 | 47 | 45 | |
| WBC, PI(D7), G1 | 0 | 0 | 0 | |
| WBC, PI(D7), G2 | 0 | 0 | 0 | |
| WBC, PI(D7), G4 | 0 | 0 | 0 | |
| PLA, PI(D7), Normal | 49 | 49 | 47 | |
| PLA, PI(D7), G1 | 0 | 1 | 1 | |
| PLA, PI(D7), G2 | 0 | 0 | 0 | |
| PLA, PI(D7), G4 | 0 | 0 | 0 | |
| ALA, PI(D7), Normal | 48 | 48 | 48 | |
| ALA, PI(D7), G1 | 0 | 0 | 0 | |
| ALA, PI(D7), G2 | 0 | 0 | 0 | |
| ALA, PI(D7), G4 | 0 | 0 | 0 | |

| | | | | |
|-----------------------|----|----|----|--|
| CREA PI(D7), Normal | 48 | 48 | 49 | |
| CREA PI(D7), G1 | 0 | 0 | 0 | |
| CREA PI(D7), G2 | 0 | 0 | 0 | |
| CREA PI(D7), G4 | 0 | 0 | 0 | |
| Haem, PI(D7), Missing | 1 | 2 | 0 | |
| WBC, PI(D7), Missing | 4 | 3 | 5 | |
| PLA, PI(D7), Missing | 0 | 0 | 1 | |
| ALA, PI(D7), Missing | 2 | 2 | 2 | |
| CREA, PI(D7), Missing | 2 | 2 | 1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers

| | |
|-----------------|--|
| End point title | Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers ^[50] |
|-----------------|--|

End point description:

Levels assessed for Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA) were: normal, grade 1 (G1), grade 2 (G2) and grade 4 (G4). Values that did not fall under normal levels or assessed grades were missing.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Seven days post Dose 2 [PII(D37)]

Notes:

[50] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Menjugate Group |
|-----------------------------|-----------------------|--|--|-------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 50 | 49 | 52 | 50 |
| Units: Subjects | | | | |
| Haem, PII(D37), Normal | 47 | 45 | 0 | 47 |
| Haem, PII(D37), G1 | 1 | 0 | 0 | 1 |
| Haem, PII(D37), G2 | 0 | 0 | 0 | 0 |
| Haem, PII(D37), G4 | 0 | 0 | 0 | 0 |
| WBC, PII(D37), Normal | 42 | 44 | 0 | 44 |
| WBC, PII(D37), G1 | 0 | 0 | 0 | 0 |
| WBC, PII(D37), G2 | 0 | 0 | 0 | 0 |
| WBC, PII(D37), G4 | 0 | 0 | 0 | 0 |
| PLA, PII(D37), Normal | 47 | 45 | 0 | 48 |
| PLA, PII(D37), G1 | 1 | 0 | 0 | 0 |
| PLA, PII(D37), G2 | 0 | 0 | 0 | 0 |
| PLA, PII(D37), G4 | 0 | 0 | 0 | 0 |

| | | | | |
|-------------------------|----|----|----|----|
| ALA, PII(D37), Normal | 48 | 46 | 0 | 48 |
| ALA, PII(D37), G1 | 0 | 0 | 0 | 0 |
| ALA, PII(D37), G2 | 0 | 0 | 0 | 0 |
| ALA, PII(D37), G4 | 0 | 0 | 0 | 0 |
| CREA PII(D37), Normal | 48 | 46 | 0 | 48 |
| CREA PII(D37), G1 | 0 | 0 | 0 | 0 |
| CREA PII(D37), G2 | 0 | 0 | 0 | 0 |
| CREA PII(D37), G4 | 0 | 0 | 0 | 0 |
| Haem, PII(D36), Missing | 2 | 4 | 52 | 2 |
| WBC, PII(D36), Missing | 8 | 5 | 52 | 6 |
| PLA, PII(D36), Missing | 2 | 4 | 52 | 2 |
| ALA, PII(D36), Missing | 2 | 3 | 52 | 2 |
| CREA, PII(D36), Missing | 2 | 3 | 52 | 2 |

| End point values | Control Tritanrix + Prevnar + Polio Sabin Group | | | |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 49 | | | |
| Units: Subjects | | | | |
| Haem, PII(D37), Normal | 47 | | | |
| Haem, PII(D37), G1 | 0 | | | |
| Haem, PII(D37), G2 | 0 | | | |
| Haem, PII(D37), G4 | 0 | | | |
| WBC, PII(D37), Normal | 44 | | | |
| WBC, PII(D37), G1 | 0 | | | |
| WBC, PII(D37), G2 | 0 | | | |
| WBC, PII(D37), G4 | 0 | | | |
| PLA, PII(D37), Normal | 47 | | | |
| PLA, PII(D37), G1 | 0 | | | |
| PLA, PII(D37), G2 | 0 | | | |
| PLA, PII(D37), G4 | 0 | | | |
| ALA, PII(D37), Normal | 47 | | | |
| ALA, PII(D37), G1 | 0 | | | |
| ALA, PII(D37), G2 | 0 | | | |
| ALA, PII(D37), G4 | 0 | | | |
| CREA PII(D37), Normal | 47 | | | |
| CREA PII(D37), G1 | 0 | | | |
| CREA PII(D37), G2 | 0 | | | |
| CREA PII(D37), G4 | 0 | | | |
| Haem, PII(D36), Missing | 2 | | | |
| WBC, PII(D36), Missing | 5 | | | |
| PLA, PII(D36), Missing | 2 | | | |
| ALA, PII(D36), Missing | 2 | | | |
| CREA, PII(D36), Missing | 2 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers

| | |
|-----------------|--|
| End point title | Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers |
|-----------------|--|

End point description:

Levels assessed for Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA) were: normal, grade 1 (G1), grade 2 (G2) and grade 4 (G4). Values that did not fall under normal levels or assessed grades were missing.

| | |
|------------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Seven days post Dose 3 [PIII(D67)] | |

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 52 | 49 | |
| Units: Subjects | | | | |
| Haem, PIII(D67), Normal | 46 | 51 | 46 | |
| Haem, PIII(D67), G1 | 0 | 0 | 0 | |
| Haem, PIII(D67), G2 | 0 | 0 | 0 | |
| Haem, PIII(D67), G4 | 0 | 0 | 0 | |
| WBC, PIII(D67), Normal | 44 | 49 | 46 | |
| WBC, PIII(D67), G1 | 0 | 0 | 0 | |
| WBC, PIII(D67), G2 | 0 | 0 | 0 | |
| WBC, PIII(D67), G4 | 0 | 0 | 0 | |
| PLA, PIII(D67), Normal | 46 | 51 | 46 | |
| PLA, PIII(D67), G1 | 0 | 0 | 0 | |
| PLA, PIII(D67), G2 | 0 | 0 | 0 | |
| PLA, PIII(D67), G4 | 0 | 0 | 0 | |
| ALA, PIII(D67), Normal | 46 | 51 | 45 | |
| ALA, PIII(D67), G1 | 0 | 1 | 0 | |
| ALA, PIII(D67), G2 | 0 | 0 | 0 | |
| ALA, PIII(D67), G4 | 0 | 0 | 0 | |
| CREA PIII(D67), Normal | 46 | 52 | 45 | |
| CREA PIII(D67), G1 | 0 | 0 | 0 | |
| CREA PIII(D67), G2 | 0 | 0 | 0 | |
| CREA PIII(D67), G4 | 0 | 0 | 0 | |
| Haem, PIII(D67), Missing | 3 | 1 | 3 | |
| WBC, PIII(D67), Missing | 5 | 3 | 3 | |
| PLA, PIII(D67), Missing | 3 | 1 | 3 | |
| ALA, PIII(D67), Missing | 3 | 0 | 4 | |
| CREA, PIII(D67), Missing | 3 | 0 | 4 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers

| | |
|-----------------|--|
| End point title | Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers ^[51] |
|-----------------|--|

End point description:

Levels assessed for Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA) were: normal, grade 1 (G1), grade 2 (G2) and grade 4 (G4). Values that did not fall under normal levels or assessed grades were missing.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

One Month post Dose 1 [PI(M1)]

Notes:

[51] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group, the SB692342 1 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | SB692342 1 dose Group | Control Menjugate Group | |
|-----------------------------|-----------------------|-----------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 50 | 50 | 50 | |
| Units: Subjects | | | | |
| Haem, PI(M1), Normal | 0 | 45 | 0 | |
| Haem, PI(M1), G1 | 0 | 2 | 0 | |
| Haem, PI(M1), G2 | 0 | 0 | 0 | |
| Haem, PI(M1), G4 | 0 | 0 | 0 | |
| WBC, PI(M1), Normal | 0 | 46 | 0 | |
| WBC, PI(M1), G1 | 0 | 0 | 0 | |
| WBC, PI(M1), G2 | 0 | 0 | 0 | |
| WBC, PI(M1), G4 | 0 | 0 | 0 | |
| PLA, PI(M1), Normal | 0 | 47 | 0 | |
| PLA, PI(M1), G1 | 0 | 0 | 0 | |
| PLA, PI(M1), G2 | 0 | 0 | 0 | |
| PLA, PI(M1), G4 | 0 | 0 | 0 | |
| ALA, PI(M1), Normal | 0 | 42 | 0 | |
| ALA, PI(M1), G1 | 0 | 0 | 0 | |
| ALA, PI(M1), G2 | 0 | 0 | 0 | |
| ALA, PI(M1), G4 | 0 | 0 | 0 | |
| CREA PI(M1), Normal | 0 | 42 | 0 | |
| CREA PI(M1), G1 | 0 | 0 | 0 | |
| CREA PI(M1), G2 | 0 | 0 | 0 | |

| | | | | |
|-----------------------|----|---|----|--|
| CREA, PI(M1), G4 | 0 | 0 | 0 | |
| Haem, PI(M1), Missing | 50 | 3 | 50 | |
| WBC, PI(M1), Missing | 50 | 4 | 50 | |
| PLA, PI(M1), Missing | 50 | 3 | 50 | |
| ALA, PI(M1), Missing | 50 | 8 | 50 | |
| CREA, PI(M1), Missing | 50 | 8 | 50 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers

| | |
|-----------------|--|
| End point title | Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers ^[52] |
|-----------------|--|

End point description:

Levels assessed for Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA) were: normal, grade 1 (G1), grade 2 (G2) and grade 4 (G4). Values that did not fall under normal levels or assessed grades were missing.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

One Month post Dose 2 [PII(M2)]

Notes:

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | Control Menjugate Group | | |
|-----------------------------|-----------------------|-------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 50 | 50 | | |
| Units: Subjects | | | | |
| Haem, PII(M2), Normal | 47 | 44 | | |
| Haem, PII(M2), G1 | 0 | 0 | | |
| Haem, PII(M2), G2 | 0 | 0 | | |
| Haem, PII(M2), G4 | 0 | 0 | | |
| WBC, PII(M2), Normal | 45 | 41 | | |
| WBC, PII(M2), G1 | 0 | 0 | | |
| WBC, PII(M2), G2 | 0 | 0 | | |
| WBC, PII(M2), G4 | 0 | 0 | | |
| PLA, PII(M2), Normal | 47 | 44 | | |
| PLA, PII(M2), G1 | 0 | 0 | | |
| PLA, PII(M2), G2 | 0 | 0 | | |
| PLA, PII(M2), G4 | 0 | 0 | | |
| ALA, PII(M2), Normal | 42 | 36 | | |
| ALA, PII(M2), G1 | 0 | 0 | | |
| ALA, PII(M2), G2 | 0 | 0 | | |
| ALA, PII(M2), G4 | 0 | 0 | | |

| | | | | |
|------------------------|----|----|--|--|
| CREA PII(M2), Normal | 42 | 36 | | |
| CREA PII(M2), G1 | 0 | 0 | | |
| CREA PII(M2), G2 | 0 | 0 | | |
| CREA PII(M2), G4 | 0 | 0 | | |
| Haem, PII(M2), Missing | 3 | 6 | | |
| WBC, PII(M2), Missing | 5 | 9 | | |
| PLA, PII(M2), Missing | 3 | 6 | | |
| ALA, PII(M2), Missing | 8 | 14 | | |
| CREA, PII(M2), Missing | 8 | 14 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers

| | |
|---|--|
| End point title | Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers |
| End point description: | |
| Levels assessed for Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA) were: normal, grade 1 (G1), grade 2 (G2) and grade 4 (G4). Values that did not fall under normal levels or assessed grades were missing. | |
| End point type | Secondary |
| End point timeframe: | |
| One Month post Dose 3 [PIII(M3)] | |

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 52 | 49 | |
| Units: Subjects | | | | |
| Haem, PIII(M3), Normal | 46 | 49 | 44 | |
| Haem, PIII(M3), G1 | 0 | 0 | 0 | |
| Haem, PIII(M3), G2 | 0 | 0 | 0 | |
| Haem, PIII(M3), G4 | 0 | 0 | 0 | |
| WBC, PIII(M3), Normal | 45 | 48 | 43 | |
| WBC, PIII(M3), G1 | 0 | 0 | 0 | |
| WBC, PIII(M3), G2 | 0 | 0 | 0 | |
| WBC, PIII(M3), G4 | 0 | 0 | 0 | |
| PLA, PIII(M3), Normal | 46 | 48 | 44 | |
| PLA, PIII(M3), G1 | 0 | 0 | 0 | |
| PLA, PIII(M3), G2 | 0 | 0 | 0 | |
| PLA, PIII(M3), G4 | 0 | 0 | 0 | |
| ALA, PIII(M3), Normal | 46 | 50 | 44 | |
| ALA, PIII(M3), G1 | 0 | 0 | 0 | |

| | | | | |
|-------------------------|----|----|----|--|
| ALA, PIII(M3), G2 | 0 | 0 | 0 | |
| ALA, PIII(M3), G4 | 0 | 0 | 0 | |
| CREA PIII(M3), Normal | 46 | 50 | 44 | |
| CREA PIII(M3), G1 | 0 | 0 | 0 | |
| CREA PIII(M3), G2 | 0 | 0 | 0 | |
| CREA PIII(M3), G4 | 0 | 0 | 0 | |
| Haem, PIII(M3), Missing | 3 | 3 | 5 | |
| WBC, PIII(M3), Missing | 4 | 4 | 6 | |
| PLA, PIII(M3), Missing | 3 | 3 | 5 | |
| ALA, PIII(M3), Missing | 3 | 2 | 5 | |
| CREA, PIII(M3), Missing | 3 | 2 | 5 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers

| | |
|-----------------|--|
| End point title | Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers ^[53] |
|-----------------|--|

End point description:

Levels assessed for Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA) were : normal, grade 1 (G1), grade 2 (G2) and grade 4 (G4). Values that did not fall under normal levels or assessed grades were missing.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Six Months post Dose 1 [PI(M6)]

Notes:

[53] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 1 dose Group from the baseline period.

| End point values | SB692342 1 dose Group | | | |
|-----------------------------|-----------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: Subjects | | | | |
| Haem, PI(M6), Normal | 41 | | | |
| Haem, PI(M6), G1 | 4 | | | |
| Haem, PI(M6), G2 | 1 | | | |
| Haem, PI(M6), G4 | 0 | | | |
| WBC, PI(M6), Normal | 45 | | | |
| WBC, PI(M6), G1 | 0 | | | |
| WBC, PI(M6), G2 | 0 | | | |
| WBC, PI(M6), G4 | 0 | | | |
| PLA, PI(M6), Normal | 46 | | | |
| PLA, PI(M6), G1 | 0 | | | |
| PLA, PI(M6), G2 | 0 | | | |
| PLA, PI(M6), G4 | 0 | | | |

| | | | | |
|-----------------------|----|--|--|--|
| ALA, PI(M6), Normal | 45 | | | |
| ALA, PI(M6), G1 | 1 | | | |
| ALA, PI(M6), G2 | 0 | | | |
| ALA, PI(M6), G4 | 0 | | | |
| CREA PI(M6), Normal | 46 | | | |
| CREA PI(M6), G1 | 0 | | | |
| CREA PI(M6), G2 | 0 | | | |
| CREA PI(M6), G4 | 0 | | | |
| Haem, PI(M6), Missing | 4 | | | |
| WBC, PI(M6), Missing | 5 | | | |
| PLA, PI(M6), Missing | 4 | | | |
| ALA, PI(M6), Missing | 4 | | | |
| CREA, PI(M6), Missing | 4 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers

| | |
|-----------------|--|
| End point title | Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers ^[54] |
|-----------------|--|

End point description:

Levels assessed for Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA) were: normal, grade 1 (G1), grade 2 (G2) and grade 4 (G4). Values that did not fall under normal levels or assessed grades were missing.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Six Months post Dose 2 [PII(M7)]

Notes:

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | Control Menjugate Group | | |
|-----------------------------|-----------------------|-------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 50 | 50 | | |
| Units: Subjects | | | | |
| Haem, PII(M7), Normal | 42 | 41 | | |
| Haem, PII(M7), G1 | 3 | 3 | | |
| Haem, PII(M7),G2 | 0 | 0 | | |
| Haem, PII(M7),G4 | 0 | 0 | | |
| WBC, PII(M7), Normal | 42 | 44 | | |
| WBC, PII(M7), G1 | 0 | 0 | | |
| WBC, PII(M7), G2 | 0 | 0 | | |
| WBC, PII(M7), G4 | 0 | 0 | | |
| PLA, PII(M7), Normal | 45 | 44 | | |

| | | | | |
|------------------------|----|----|--|--|
| PLA, PII(M7), G1 | 0 | 0 | | |
| PLA, PII(M7), G2 | 0 | 0 | | |
| PLA, PII(M7), G4 | 0 | 0 | | |
| ALA, PII(M7), Normal | 43 | 43 | | |
| ALA, PII(M7), G1 | 0 | 0 | | |
| ALA, PII(M7), G2 | 0 | 0 | | |
| ALA, PII(M7), G4 | 0 | 0 | | |
| CREA PII(M7), Normal | 43 | 43 | | |
| CREA PII(M7), G1 | 0 | 0 | | |
| CREA PII(M7), G2 | 0 | 0 | | |
| CREA PII(M7), G4 | 0 | 0 | | |
| Haem, PII(M7), Missing | 5 | 6 | | |
| WBC, PII(M7), Missing | 8 | 6 | | |
| PLA, PII(M7), Missing | 5 | 6 | | |
| ALA, PII(M7), Missing | 7 | 7 | | |
| CREA, PII(M7), Missing | 7 | 7 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers

| | |
|-----------------|--|
| End point title | Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers |
|-----------------|--|

End point description:

Levels assessed for Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA) were: normal, grade 1 (G1), grade 2 (G2) and grade 4 (G4). Values that did not fall under normal levels or assessed grades were missing.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Six Months post Dose 3 [PIII(M8)]

| End point values | SB692392 2 dose + Tritanrix + Pevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group | Control Tritanrix + Pevnar + Polio Sabin Group | |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 52 | 49 | |
| Units: Subjects | | | | |
| Haem, PIII(M8), Normal | 43 | 47 | 44 | |
| Haem, PIII(M8), G1 | 1 | 4 | 2 | |
| Haem, PIII(M8), G2 | 0 | 0 | 0 | |
| Haem, PIII(M8), G4 | 0 | 0 | 0 | |
| WBC, PIII(M8), Normal | 41 | 47 | 41 | |
| WBC, PIII(M8), G1 | 0 | 0 | 0 | |
| WBC, PIII(M8), G2 | 0 | 0 | 0 | |

| | | | | |
|-------------------------|----|----|----|--|
| WBC, PIII(M8), G4 | 0 | 0 | 0 | |
| PLA, PIII(M8), Normal | 44 | 50 | 46 | |
| PLA, PIII(M8), G1 | 0 | 1 | 0 | |
| PLA, PIII(M8), G2 | 0 | 0 | 0 | |
| PLA, PIII(M8), G4 | 0 | 0 | 0 | |
| ALA, PIII(M8), Normal | 43 | 50 | 46 | |
| ALA, PIII(M8), G1 | 1 | 0 | 0 | |
| ALA, PIII(M8), G2 | 0 | 0 | 0 | |
| ALA, PIII(M8), G4 | 0 | 0 | 0 | |
| CREA PIII(M8), Normal | 43 | 51 | 46 | |
| CREA PIII(M8), G1 | 0 | 0 | 0 | |
| CREA PIII(M8), G2 | 0 | 0 | 0 | |
| CREA PIII(M8), G4 | 0 | 0 | 0 | |
| Haem, PIII(M8), Missing | 5 | 1 | 3 | |
| WBC, PIII(M8), Missing | 8 | 5 | 8 | |
| PLA, PIII(M8), Missing | 5 | 1 | 3 | |
| ALA, PIII(M8), Missing | 5 | 1 | 3 | |
| CREA, PIII(M8), Missing | 6 | 1 | 3 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers

| | |
|-----------------|--|
| End point title | Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers ^[55] |
|-----------------|--|

End point description:

Levels assessed for Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA) were: normal, grade 1 (G1), grade 2 (G2) and grade 4 (G4). Values that did not fall under normal levels or assessed grades were missing.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Six Months post Dose 3 [PIII(M13)]

Notes:

[55] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | Control Menjugate Group | | |
|-----------------------------|-----------------------|-------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 50 | 50 | | |
| Units: Subjects | | | | |
| Haem, PIII(M13), Normal | 0 | 43 | | |
| Haem, PIII(M13), G1 | 0 | 1 | | |
| Haem, PIII(M13), G2 | 0 | 0 | | |
| Haem, PIII(M13), G4 | 0 | 0 | | |

| | | | | |
|--------------------------|----|----|--|--|
| WBC, PIII(M13), Normal | 0 | 42 | | |
| WBC, PIII(M13), G1 | 0 | 0 | | |
| WBC, PIII(M13), G2 | 0 | 0 | | |
| WBC, PIII(M13), G4 | 0 | 0 | | |
| PLA, PIII(M13), Normal | 0 | 44 | | |
| PLA, PIII(M13), G1 | 0 | 0 | | |
| PLA, PIII(M13), G2 | 0 | 0 | | |
| PLA, PIII(M13), G4 | 0 | 0 | | |
| ALA, PIII(M13), Normal | 0 | 44 | | |
| ALA, PIII(M13), G1 | 0 | 0 | | |
| ALA, PIII(M13), G2 | 0 | 0 | | |
| ALA, PIII(M13), G4 | 0 | 0 | | |
| CREA PIII(M13), Normal | 0 | 44 | | |
| CREA PIII(M13), G1 | 0 | 0 | | |
| CREA PIII(M13), G2 | 0 | 0 | | |
| CREA PIII(M13), G4 | 0 | 0 | | |
| Haem, PIII(M13), Missing | 50 | 6 | | |
| WBC, PIII(M13), Missing | 50 | 8 | | |
| PLA, PIII(M13), Missing | 50 | 6 | | |
| ALA, PIII(M13), Missing | 50 | 6 | | |
| CREA, PIII(M13), Missing | 50 | 6 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers

| | |
|-----------------|--|
| End point title | Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers ^[56] |
|-----------------|--|

End point description:

Levels assessed for Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA) were: normal, grade 1 (G1), grade 2 (G2) and grade 4 (G4). Values that did not fall under normal levels or assessed grades were missing.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Twelve Months post Dose 1 [PI(M12)]

Notes:

[56] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 1 dose Group from the baseline period.

| | | | | |
|-----------------------------|-----------------------|--|--|--|
| End point values | SB692342 1 dose Group | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: Subjects | | | | |
| Haem, PI(M12), Normal | 47 | | | |
| Haem, PI(M12), G1 | 2 | | | |

| | | | | |
|------------------------|----|--|--|--|
| Haem, PI(M12), G2 | 0 | | | |
| Haem, PI(M12), G4 | 0 | | | |
| WBC, PI(M12), Normal | 48 | | | |
| WBC, PI(M12), G1 | 0 | | | |
| WBC, PI(M12), G2 | 0 | | | |
| WBC, PI(M12), G4 | 0 | | | |
| PLA, PI(M12), Normal | 48 | | | |
| PLA, PI(M12), G1 | 1 | | | |
| PLA, PI(M12), G2 | 0 | | | |
| PLA, PI(M12), G4 | 0 | | | |
| ALA, PI(M12), Normal | 46 | | | |
| ALA, PI(M12), G1 | 2 | | | |
| ALA, PI(M12), G2 | 1 | | | |
| ALA, PI(M12), G4 | 0 | | | |
| CREA PI(M12), Normal | 49 | | | |
| CREA PI(M12), G1 | 0 | | | |
| CREA PI(M12), G2 | 0 | | | |
| CREA PI(M12), G4 | 0 | | | |
| Haem, PI(M12), Missing | 1 | | | |
| WBC, PI(M12), Missing | 2 | | | |
| PLA, PI(M12), Missing | 1 | | | |
| ALA, PI(M12), Missing | 1 | | | |
| CREA, PI(M12), Missing | 1 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers

| | |
|-----------------|--|
| End point title | Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers ^[57] |
|-----------------|--|

End point description:

Levels assessed for Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA) were: normal, grade 1 (G1), grade 2 (G2) and grade 4 (G4). Values that did not fall under normal levels or assessed grades were missing.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Twelve Months post Dose 2 [PII(M13)]

Notes:

[57] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the SB692342 2 dose Group and the Control Menjugate Group from the baseline period.

| End point values | SB692342 2 dose Group | Control Menjugate Group | | |
|-----------------------------|-----------------------|-------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 50 | 50 | | |
| Units: Subjects | | | | |
| Haem, PII(M13), Normal | 41 | 0 | | |
| Haem, PII(M13), G1 | 4 | 0 | | |
| Haem, PII(M13), G2 | 1 | 0 | | |
| Haem, PII(M13), G4 | 0 | 0 | | |
| WBC, PII(M13), Normal | 43 | 0 | | |
| WBC, PII(M13), G1 | 0 | 0 | | |
| WBC, PII(M13), G2 | 0 | 0 | | |
| WBC, PII(M13), G4 | 0 | 0 | | |
| PLA, PII(M13), Normal | 46 | 0 | | |
| PLA, PII(M13), G1 | 0 | 0 | | |
| PLA, PII(M13), G2 | 0 | 0 | | |
| PLA, PII(M13), G4 | 0 | 0 | | |
| ALA, PII(M13), Normal | 45 | 0 | | |
| ALA, PII(M13), G1 | 1 | 0 | | |
| ALA, PII(M13), G2 | 0 | 0 | | |
| ALA, PII(M13), G4 | 0 | 0 | | |
| CREA PII(M13), Normal | 46 | 0 | | |
| CREA PII(M13), G1 | 0 | 0 | | |
| CREA PII(M13), G2 | 0 | 0 | | |
| CREA PII(M13), G4 | 0 | 0 | | |
| Haem, PII(M13), Missing | 4 | 50 | | |
| WBC, PII(M13), Missing | 7 | 50 | | |
| PLA, PII(M13), Missing | 4 | 50 | | |
| ALA, PII(M13), Missing | 4 | 50 | | |
| CREA, PII(M13), Missing | 4 | 50 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers

| | |
|-----------------|--|
| End point title | Number of Subjects with Normal, G1, G2, or G4 Haematological and Biochemical Markers |
|-----------------|--|

End point description:

Levels assessed for Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA) were: normal, grade 1 (G1), grade 2 (G2) and grade 4 (G4). Values that did not fall under normal levels or assessed grades were missing.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Twelve Months post Dose 3 [PIII(M14)]

| End point values | SB692392 2 dose + Tritanrix + Prevnam + Polio Sabin Group | SB692392 1 dose + Tritanrix + Prevnam + Polio Sabin Group | Control Tritanrix + Prevnam + Polio Sabin Group | |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 52 | 49 | |
| Units: Subjects | | | | |
| Haem, PIII(M14), Normal | 38 | 46 | 37 | |
| Haem, PIII(M14), G1 | 6 | 5 | 8 | |
| Haem, PIII(M14), G2 | 0 | 0 | 0 | |
| Haem, PIII(M14), G4 | 0 | 0 | 0 | |
| WBC, PIII(M14), Normal | 42 | 48 | 42 | |
| WBC, PIII(M14), G1 | 0 | 0 | 0 | |
| WBC, PIII(M14), G2 | 0 | 0 | 0 | |
| WBC, PIII(M14), G4 | 0 | 0 | 0 | |
| PLA, PIII(M14), Normal | 44 | 51 | 44 | |
| PLA, PIII(M14), G1 | 0 | 0 | 0 | |
| PLA, PIII(M14), G2 | 0 | 0 | 0 | |
| PLA, PIII(M14), G4 | 0 | 0 | 0 | |
| ALA, PIII(M14), Normal | 43 | 51 | 43 | |
| ALA, PIII(M14), G1 | 1 | 0 | 1 | |
| ALA, PIII(M14), G2 | 0 | 0 | 0 | |
| ALA, PIII(M14), G4 | 0 | 0 | 0 | |
| CREA PIII(M14), Normal | 44 | 51 | 44 | |
| CREA PIII(M14), G1 | 0 | 0 | 0 | |
| CREA PIII(M14), G2 | 0 | 0 | 0 | |
| CREA PIII(M14), G4 | 0 | 0 | 0 | |
| Haem, PIII(M14), Missing | 5 | 1 | 4 | |
| WBC, PIII(M14), Missing | 7 | 4 | 7 | |
| PLA, PIII(M14), Missing | 5 | 1 | 4 | |
| ALA, PIII(M14), Missing | 5 | 1 | 5 | |
| CREA, PIII(M14), Missing | 5 | 1 | 5 | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms: during the 7-day post-vaccination period; Unsolicited AEs: during the 30-day post-vaccination period; SAEs: from study start (Day 0) up to one month post-vaccination and from Day 0 up to 12 months post last vaccination.

Adverse event reporting additional description:

Other Adverse Events were collected from all subjects with at least one administered dose with safety follow-up and who completed their symptom sheet.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 14.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-----------------------|
| Reporting group title | SB692342 2 dose Group |
|-----------------------|-----------------------|

Reporting group description:

Subjects received two doses of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, 1 month apart, on a 0, 1 month schedule after having completed their primary EPI regimen.

| | |
|-----------------------|-----------------------|
| Reporting group title | SB692392 1 dose Group |
|-----------------------|-----------------------|

Reporting group description:

Subjects received one dose of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, at Month 0, after having completed their primary EPI regimen.

| | |
|-----------------------|-------------------------|
| Reporting group title | Control Menjugate Group |
|-----------------------|-------------------------|

Reporting group description:

Subjects received three doses of the control Menjugate vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, on a 0, 1, 7 months schedule. The first two doses were administered 1 month apart during the primary vaccination phase and the third dose was administered 6 months after the last primary vaccination dose.

| | |
|-----------------------|---|
| Reporting group title | SB692392 2dose + Tritanrix + Pevnar + Polio Sabin Group |
|-----------------------|---|

Reporting group description:

Subjects received two doses of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, 1 month apart, concomitantly with the last two doses of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered intramuscularly in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Pevnar vaccine, administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Pevnar vaccines approximately 1 year after their last dose.

| | |
|-----------------------|--|
| Reporting group title | SB692392 1 dose + Tritanrix + Pevnar + Polio Sabin Group |
|-----------------------|--|

Reporting group description:

Subjects received one dose of SB692342 vaccine (0,5 mL), administered intramuscularly in the anterolateral region of the right thigh, concomitantly with the last dose of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered intramuscularly in the anterolateral region of the left thigh, Polio Sabin™ vaccine, administered orally, and Pevnar vaccine, administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Pevnar vaccines approximately 1 year after their last dose.

| | |
|-----------------------|--|
| Reporting group title | Control Tritanrix + Pevnar + Polio Sabin Group |
|-----------------------|--|

Reporting group description:

Subjects received three doses of the primary EPI regimen containing Tritanrix HepB+Hiberix vaccine, administered in the anterolateral region of the left thigh, Polio Sabin vaccine, administered orally, and Pevnar vaccine administered intramuscularly in the right arm, on a 0, 1, 2 months schedule. All subjects received a booster dose of the Tritanrix HepB+Hiberix, Polio Sabin and Pevnar vaccines approximately 1 year after their last dose.

| Serious adverse events | SB692342 2 dose Group | SB692392 1 dose Group | Control Menjugate Group |
|--|-----------------------|-----------------------|-------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 50 (4.00%) | 3 / 50 (6.00%) | 3 / 50 (6.00%) |
| number of deaths (all causes) | 0 | 0 | 1 |
| number of deaths resulting from adverse events | | | |
| Injury, poisoning and procedural complications | | | |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 1 / 50 (2.00%) | 0 / 50 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 0 / 50 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 1 / 50 (2.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 1 / 50 (2.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Sepsis | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 1 / 50 (2.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Bronchopneumonia | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 2 / 50 (4.00%) | 1 / 50 (2.00%) | 1 / 50 (2.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 1 / 50 (2.00%) | 0 / 50 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebral malaria | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 1 / 50 (2.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malaria | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 50 (0.00%) | 0 / 50 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group | Control Tritanrix + Prevnar + Polio Sabin Group |
|--|--|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 49 (2.04%) | 1 / 52 (1.92%) | 1 / 49 (2.04%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Injury, poisoning and procedural complications | | | |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 52 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 1 / 52 (1.92%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 52 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 52 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Sepsis | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 52 (0.00%) | 1 / 49 (2.04%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchopneumonia | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 52 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 49 (2.04%) | 0 / 52 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebral malaria | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 52 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malaria | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 52 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | SB692342 2 dose Group | SB692392 1 dose Group | Control Menjugate Group |
|---|------------------------------|------------------------------|--------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 33 / 50 (66.00%) | 22 / 50 (44.00%) | 31 / 50 (62.00%) |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed ^[1] | 3 / 50 (6.00%) | 1 / 50 (2.00%) | 4 / 50 (8.00%) |
| occurrences (all) | 3 | 1 | 4 |
| Pain | | | |
| subjects affected / exposed ^[2] | 6 / 50 (12.00%) | 2 / 50 (4.00%) | 6 / 50 (12.00%) |
| occurrences (all) | 6 | 2 | 6 |
| Swelling | | | |
| subjects affected / exposed ^[3] | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 0 / 50 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Drowsiness | | | |
| subjects affected / exposed ^[4] | 2 / 50 (4.00%) | 0 / 50 (0.00%) | 1 / 50 (2.00%) |
| occurrences (all) | 2 | 0 | 1 |
| Irritability | | | |
| subjects affected / exposed ^[5] | 3 / 50 (6.00%) | 0 / 50 (0.00%) | 2 / 50 (4.00%) |
| occurrences (all) | 3 | 0 | 2 |
| Loss of appetite | | | |
| subjects affected / exposed ^[6] | 3 / 50 (6.00%) | 0 / 50 (0.00%) | 1 / 50 (2.00%) |
| occurrences (all) | 3 | 0 | 1 |
| Temperature(Axillary) | | | |
| subjects affected / exposed ^[7] | 19 / 50 (38.00%) | 5 / 50 (10.00%) | 13 / 50 (26.00%) |
| occurrences (all) | 19 | 5 | 13 |
| Eye disorders | | | |
| Conjunctivitis | | | |
| subjects affected / exposed ^[8] | 0 / 50 (0.00%) | 0 / 50 (0.00%) | 1 / 50 (2.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed ^[9] | 8 / 50 (16.00%) | 5 / 50 (10.00%) | 2 / 50 (4.00%) |
| occurrences (all) | 8 | 5 | 2 |
| Infections and infestations | | | |
| Respiratory tract infection | | | |

| | | | |
|---|------------------|------------------|------------------|
| subjects affected / exposed ^[10] | 21 / 50 (42.00%) | 14 / 50 (28.00%) | 19 / 50 (38.00%) |
| occurrences (all) | 21 | 14 | 19 |

| Non-serious adverse events | SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group | SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group | Control Tritanrix + Prevnar + Polio Sabin Group |
|---|--|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 34 / 49 (69.39%) | 22 / 52 (42.31%) | 26 / 49 (53.06%) |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed ^[1] | 0 / 47 (0.00%) | 2 / 52 (3.85%) | 0 / 48 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Pain | | | |
| subjects affected / exposed ^[2] | 10 / 47 (21.28%) | 13 / 52 (25.00%) | 13 / 48 (27.08%) |
| occurrences (all) | 10 | 13 | 13 |
| Swelling | | | |
| subjects affected / exposed ^[3] | 6 / 47 (12.77%) | 8 / 52 (15.38%) | 8 / 48 (16.67%) |
| occurrences (all) | 6 | 8 | 8 |
| Drowsiness | | | |
| subjects affected / exposed ^[4] | 3 / 47 (6.38%) | 3 / 52 (5.77%) | 0 / 48 (0.00%) |
| occurrences (all) | 3 | 3 | 0 |
| Irritability | | | |
| subjects affected / exposed ^[5] | 8 / 47 (17.02%) | 5 / 52 (9.62%) | 4 / 48 (8.33%) |
| occurrences (all) | 8 | 5 | 4 |
| Loss of appetite | | | |
| subjects affected / exposed ^[6] | 3 / 47 (6.38%) | 2 / 52 (3.85%) | 0 / 48 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| Temperature(Axillary) | | | |
| subjects affected / exposed ^[7] | 18 / 47 (38.30%) | 9 / 52 (17.31%) | 12 / 48 (25.00%) |
| occurrences (all) | 18 | 9 | 12 |
| Eye disorders | | | |
| Conjunctivitis | | | |
| subjects affected / exposed ^[8] | 0 / 47 (0.00%) | 0 / 52 (0.00%) | 3 / 48 (6.25%) |
| occurrences (all) | 0 | 0 | 3 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed ^[9] | 5 / 47 (10.64%) | 1 / 52 (1.92%) | 3 / 48 (6.25%) |
| occurrences (all) | 5 | 1 | 3 |

| | | | |
|---|------------------|-----------------|------------------|
| Infections and infestations | | | |
| Respiratory tract infection | | | |
| subjects affected / exposed ^[10] | 15 / 47 (31.91%) | 9 / 52 (17.31%) | 14 / 48 (29.17%) |
| occurrences (all) | 15 | 9 | 14 |

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Assessment for this event for this phase was performed solely on subjects with their symptom sheets completed.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Assessment for this event for this phase was performed solely on subjects with their symptom sheets completed.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Assessment for this event for this phase was performed solely on subjects with their symptom sheets completed.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Assessment for this event for this phase was performed solely on subjects with their symptom sheets completed.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Assessment for this event for this phase was performed solely on subjects with their symptom sheets completed.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Assessment for this event for this phase was performed solely on subjects with their symptom sheets completed.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Assessment for this event for this phase was performed solely on subjects with their symptom sheets completed.

[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Assessment for this event for this phase was performed solely on subjects with their symptom sheets completed.

[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Assessment for this event for this phase was performed solely on subjects with their symptom sheets completed.

[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Assessment for this event for this phase was performed solely on subjects with their symptom sheets completed.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|---|
| 19 November 2010 | The purpose of this amendment is to apply a standard and robust methodology for the collection, documentation and safety monitoring of serious and nonserious potential immune mediated disorders (pIMDs) as adverse events of special interest occurring in subjects participating in clinical trials evaluating GSK adjuvant containing vaccines. Guidance for what is considered as to be potentially immune mediated and time period of pIMD reporting are included in this amendment. |
| 28 July 2011 | The pneumococcal conjugate vaccine (PCV) being administered as part of the EPI vaccination in this study is Prevnar (7-valent PCV). The manufacturing company (Wyeth) has stopped production and marketing of 7-valent PCV which was initially used in the study. It currently produces and markets the 13-valent PCV (Prevnar 13). The SPC shows that the 13-valent PCV can be given after the 7-valent PCV with no safety issues. Hence for the booster dose, subjects in this study will be given the 13- valent PCV. This change in formulation of the administered vaccine is not expected to have an impact on the analysis of any study endpoints. The protocol has been amended to include a description of the 13-valent PCV. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported