



Clinical trial results:

A phase III, randomized, open, active-controlled study to evaluate the safety and immunogenicity of a prime-boost schedule of the H5N1 candidate vaccine adjuvanted with AS03B administered to children aged 3 to 17 years.

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2011-004751-39 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 05 October 2012 |

Results information

| | |
|--------------------------------|--|
| Result version number | v2 |
| This version publication date | 13 May 2016 |
| First version publication date | 24 May 2015 |
| Version creation reason | <ul style="list-style-type: none">• Correction of full data set Data (typos) were corrected in 1 justification note and 1 endpoint description |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 115115 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01379937 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-000160-PIP01-07 |
| 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 | 05 October 2012 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 05 October 2012 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

Co-primary Immunogenicity Objective

- To assess the superiority of the haemagglutination inhibition (HI) antibody response against A/turkey/Turkey/01/2005 (H5N1) 10 days following H5N1 vaccination at Day 182 [1.9 µg A/turkey/Turkey/01/2005 (H5N1) HA antigen adjuvanted with AS03B] in subjects previously primed with 2 doses of heterologous A/Indonesia/5/2005 (H5N1) vaccine (Group H5N1_H5N1) versus non primed subjects (Group Havrix_H5N1).

Co-primary Safety Objective

- To evaluate the safety of the paediatric H5N1 vaccine when administered as a 2-dose primary vaccination to subjects 3 to 17 years of age in terms of occurrence of medically attended adverse events (MAEs) from Day 0 to Day 182 and to the Day 364 visit.

Protection of trial subjects:

All subjects were supervised for 30 min after vaccination administration with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel only to eligible subjects that had no contraindications to any components of the vaccines.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 28 July 2011 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|------------------|
| Country: Number of subjects enrolled | Philippines: 520 |
| Worldwide total number of subjects | 520 |
| 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) | 0 |
| Children (2-11 years) | 320 |
| Adolescents (12-17 years) | 200 |
| 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:

The study was of an overall duration 364 days for all subjects.

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|--|
| Are arms mutually exclusive? | Yes |
| Arm title | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group |

Arm description:

Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1, a booster vaccination dose of Influenza vaccine GSK1562902A Formulation 2 and 1 dose of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | H5N1 A/Indonesia/5/2005 with AS03B (Formulation 1) |
| Investigational medicinal product code | GSK1562902A |
| Other name | |
| Pharmaceutical forms | Emulsion and suspension for emulsion for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Intramuscular injection, two doses each in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 1 - Havrix / Havrix Jr Group

| | |
|--|---|
| Investigational medicinal product name | H5N1 A/turkey/Turkey/01/2005 with AS03B (Formulation 2) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Emulsion and suspension for emulsion for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Intramuscular injection, one dose each in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group

| | |
|--|--------------------------|
| Investigational medicinal product name | Havrix 1440 Adult |
| Investigational medicinal product code | |
| Other name | Havrix™ |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group

| | |
|--|------------------------|
| Investigational medicinal product name | Havrix 720 Junior |
| Investigational medicinal product code | |
| Other name | Havrix™ Junior |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group

| | |
|------------------|--|
| Arm title | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group |
|------------------|--|

Arm description:

Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | H5N1 A/Indonesia/05/2005 with AS03B (Formulation 1) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Emulsion and suspension for emulsion for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Intramuscular injection, two doses each in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 1 - Havrix / Havrix Jr Group

| | |
|--|--------------------------|
| Investigational medicinal product name | Havrix 1440 Adult |
| Investigational medicinal product code | |
| Other name | Havrix™ |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group

| | |
|--|--------------------------|
| Investigational medicinal product name | Havrix 720 Junior |
| Investigational medicinal product code | |
| Other name | Havrix™ Junior |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group

| | |
|------------------|--|
| Arm title | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group |
|------------------|--|

Arm description:

Subjects in this group received 1 dose of Influenza vaccine GSK1562902A Formulation 2 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

| | |
|--|---|
| Arm type | Active comparator |
| Investigational medicinal product name | H5N1 A/turkey/Turkey/01/2005 with AS03B (Formulation 2) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Emulsion and suspension for emulsion for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Intramuscular injection, one dose each in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group

| | |
|--|-------------------|
| Investigational medicinal product name | Havrix 1440 Adult |
| Investigational medicinal product code | |
| Other name | Havrix™ |

| | |
|---|--------------------------|
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group | |
| Investigational medicinal product name | Havrix 720 Junior |
| Investigational medicinal product code | |
| Other name | Havrix™ Junior |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group | |
| Arm title | Havrix / Havrix Jr Group |

Arm description:

Subjects in this group received 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

| | |
|---|--------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Havrix 1440 Adult |
| Investigational medicinal product code | |
| Other name | Havrix™ |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group | |
| Investigational medicinal product name | Havrix 720 Junior |
| Investigational medicinal product code | |
| Other name | Havrix™ Junior |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Intramuscular injection, one dose in GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and two doses each in GSK1562902A Formulation 1 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and Havrix / Havrix Jr Group

| Number of subjects in period 1 | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group |
|---------------------------------------|---|---|---|
| Started | 156 | 156 | 104 |
| Completed | 155 | 153 | 102 |
| Not completed | 1 | 3 | 2 |
| Consent withdrawn by subject | - | 1 | - |
| Protocol violation | - | - | - |
| Migrated/moved from study area | 1 | 2 | 2 |

| Number of subjects in period 1 | Havrix / Havrix Jr Group |
|---------------------------------------|--------------------------|
| Started | 104 |
| Completed | 103 |
| Not completed | 1 |
| Consent withdrawn by subject | - |
| Protocol violation | 1 |
| Migrated/moved from study area | - |

Baseline characteristics

Reporting groups

| | |
|-----------------------|--|
| Reporting group title | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group |
|-----------------------|--|

Reporting group description:

Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1, a booster vaccination dose of Influenza vaccine GSK1562902A Formulation 2 and 1 dose of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

| | |
|-----------------------|--|
| Reporting group title | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group |
|-----------------------|--|

Reporting group description:

Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

| | |
|-----------------------|--|
| Reporting group title | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group |
|-----------------------|--|

Reporting group description:

Subjects in this group received 1 dose of Influenza vaccine GSK1562902A Formulation 2 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

| | |
|-----------------------|--------------------------|
| Reporting group title | Havrix / Havrix Jr Group |
|-----------------------|--------------------------|

Reporting group description:

Subjects in this group received 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

| Reporting group values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group |
|---|--|--|--|
| Number of subjects | 156 | 156 | 104 |
| Age categorical Units: Subjects | | | |
| In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over | | | |
| Age continuous Units: years | | | |
| geometric mean | 9.7 | 9.4 | 9.3 |
| standard deviation | ± 4.26 | ± 3.88 | ± 3.87 |
| Gender categorical Units: Subjects | | | |
| Female | 81 | 81 | 52 |
| Male | 75 | 75 | 52 |

| Reporting group values | Havrix / Havrix Jr Group | Total | |
|------------------------|--------------------------|-------|--|
| Number of subjects | 104 | 520 | |

| | | | |
|---|--------|-----|--|
| 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) | | 0 | |
| 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: years | | | |
| geometric mean | 9.6 | | |
| standard deviation | ± 4.23 | - | |
| Gender categorical Units: Subjects | | | |
| Female | 52 | 266 | |
| Male | 52 | 254 | |

End points

End points reporting groups

| | |
|---|---|
| Reporting group title | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group |
| Reporting group description: Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1, a booster vaccination dose of Influenza vaccine GSK1562902A Formulation 2 and 1 dose of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region. | |
| Reporting group title | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group |
| Reporting group description: Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region. | |
| Reporting group title | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group |
| Reporting group description: Subjects in this group received 1 dose of Influenza vaccine GSK1562902A Formulation 2 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region. | |
| Reporting group title | Havrix / Havrix Jr Group |
| Reporting group description: Subjects in this group received 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region. | |
| Subject analysis set title | GSK1562902A Formulation 1 & 2 - Havrix/Havrix Jr pooled Group |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Pooled group of subjects who received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1, no or 1 booster dose of vaccination dose of Influenza vaccine GSK1562902A Formulation 2 and 1 or 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region. | |
| Subject analysis set title | GSK1562902A Formulation 2 - Havrix/Havrix Jr pooled Group |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Pooled group of subjects who received no or 1 dose of Influenza vaccine GSK1562902A Formulation 2 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region. | |

Primary: Haemagglutination Inhibition (HI) antibody titers for the A/Turkey/Turkey/01/2005 (H5N1) vaccine strain.

| | |
|--|---|
| End point title | Haemagglutination Inhibition (HI) antibody titers for the A/Turkey/Turkey/01/2005 (H5N1) vaccine strain. ^[1] |
| End point description: Antibody titers were expressed as Geometric mean titers (GMTs). The H5N1 vaccine strain included A/Turkey/Turkey/01/2005 antigen. The A/Turkey/Turkey/01/2005 (A/TURK) vaccine strain was administered to groups receiving the adjuvanted Influenza vaccine GSK1562902A. This outcome concerns solely subjects in the GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protocol. | |
| End point type | Primary |
| End point timeframe: At Day 192. | |

Notes:

[1] - 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: The analysis was made only on subjects receiving A/turkey/Turkey/01/2005 strain containing vaccine.

| | | | | |
|---|--|--|--|--|
| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 127 | 84 | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Haemagglutination Inhibition (HI) antibody titers | 737.6 (646.8 to 841.1) | 24.7 (19.7 to 31) | | |

Statistical analyses

| | |
|-----------------------------------|--|
| Statistical analysis title | Titer superiority of primed vs unprimed subjects |
|-----------------------------------|--|

Statistical analysis description:

To assess the superiority of the haemagglutination inhibition (HI) antibody response against A/turkey/Turkey/01/2005 (H5N1) influenza strain 10 days following GSK1562902A formulation 2 vaccination at Day 182 in subjects previously primed with 2 doses of GSK1562902A vaccine (GSK1562902A formulation 1 Group) versus non primed subjects (GSK1562902A Formulation 2 - Havrix / Havrix Jr Group).

| | |
|---|---|
| Comparison groups | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group v GSK1562902A Formulation 2 - Havrix / Havrix Jr Group |
| Number of subjects included in analysis | 211 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[2] |
| Parameter estimate | Adjusted GMT ratio |
| Point estimate | 11.84 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.3 |
| upper limit | 19.2 |

Notes:

[2] - Criteria to be used for the objective:

If the lower limit of the 2-sided 95% confidence interval (CI) for the HI Geometric mean titre (GMT) ratio at Day 192 (GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group compared to GSK1562902A Formulation 2 - Havrix / Havrix Jr Group) was greater than 1.0, then the superiority of priming vaccination will have been shown and an anamnestic immune response demonstrated.

Primary: Number of subjects with any medically attended adverse events (MAEs)

| | |
|-----------------|---|
| End point title | Number of subjects with any medically attended adverse events (MAEs) ^[3] |
|-----------------|---|

End point description:

Any = occurrence of the symptom regardless of intensity grade. This outcome concerns solely subjects in the GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protocol.

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

End point timeframe:

From Day 0 to Day 182

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 scope of this primary endpoint was descriptive, no statistical analyses were conducted.

| | | | | |
|-----------------------------|---|---|--|--|
| End point values | GSK1562902A Formulation 1 & 2 - Havrix/Havrix Jr pooled Group | GSK1562902A Formulation 2 - Havrix/Havrix Jr pooled Group | | |
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 312 | 208 | | |
| Units: Subjects | | | | |
| Any MAEs | 115 | 64 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any medically attended adverse events (MAEs)

| | |
|--|---|
| End point title | Number of subjects with any medically attended adverse events (MAEs) ^[4] |
| End point description: Any = occurrence of the symptom regardless of intensity grade. | |
| End point type | Primary |
| End point timeframe: From Day 0 to Day 364. | |

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 scope of this primary endpoint was descriptive, no statistical analyses were conducted.

| | | | | |
|-----------------------------|--|--|--|--------------------------|
| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 156 | 156 | 104 | 104 |
| Units: Subjects | | | | |
| Any MAEs | 65 | 84 | 41 | 41 |

Statistical analyses

No statistical analyses for this end point

Secondary: H5N1 HI antibody titres against the A/Indonesia/5/2005 and A/Turkey/Turkey/01/2005 (H5N1 virus) strains

| | |
|-----------------|---|
| End point title | H5N1 HI antibody titres against the A/Indonesia/5/2005 and A/Turkey/Turkey/01/2005 (H5N1 virus) strains |
|-----------------|---|

End point description:

The antibody titres were given as Geometric Mean Titer (GMT). A/Indonesia/5/2005 = A/INDO and A/Turkey/Turkey/01/2005 = A/TURK. For D192, antibody titers were tabulated for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protocol.

For D364, antibody titers were tabulated for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 1 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protocol.

| | |
|------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At Days 0, 42, 182, 192, 364 | |

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
|--|--|--|--|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 155 | 152 | 103 | 101 |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/INDO, Day 0 [N=155,152,103,101] | 5.7 (5.4 to 6) | 5.5 (5.2 to 5.8) | 5.4 (5.1 to 5.8) | 5.8 (5.3 to 6.3) |
| A/INDO, Day 42 [N=155,152,103,101] | 553.5 (490.9 to 624.1) | 595 (522.1 to 678.2) | 5.6 (5.2 to 6) | 6.2 (5.6 to 7) |
| A/INDO, Day 182 [N=155,152,103,101] | 52.2 (47.7 to 57.1) | 54.1 (49.5 to 59.1) | 5.1 (5 to 5.2) | 5.6 (5.3 to 6) |
| A/INDO, Day 192 [N=127,NA,45,NA] | 674.1 (595 to 763.8) | 0 (0 to 0) | 7.6 (6.7 to 8.5) | 0 (0 to 0) |
| A/INDO, Day 364 [N=151,147,100,NA] | 205.5 (183.3 to 230.4) | 40.4 (36.8 to 44.5) | 8.5 (7.6 to 9.4) | 0 (0 to 0) |
| A/TURK, Day 0 [N=155,152,103,101] | 7 (6.3 to 7.7) | 6.4 (5.9 to 7) | 6.1 (5.6 to 6.8) | 7.2 (6.3 to 8.2) |
| A/TURK, Day 42 [N=155,152,103,101] | 193 (172.1 to 216.5) | 240.3 (188.1 to 240.3) | 6.9 (6.9 to 7.9) | 8.5 (7.2 to 10) |
| A/TURK, Day 182 [N=127,152,84,101] | 39.6 (35.8 to 43.8) | 42.5 (38.9 to 46.4) | 6 (5.5 to 6.5) | 7 (6.1 to 8) |
| A/TURK, Day 364 [N=151,147,100,NA] | 215.1 (190.3 to 243.3) | 35.4 (32.2 to 39) | 18.4 (16.3 to 20.9) | 0 (0 to 0) |

Statistical analyses

No statistical analyses for this end point

Secondary: H5N1 HI neutralizing antibody titres against the A/Indonesia/5/2005 and A/turkey/Turkey/01/2005 (H5N1 virus) strains

| | |
|-----------------|--|
| End point title | H5N1 HI neutralizing antibody titres against the A/Indonesia/5/2005 and A/turkey/Turkey/01/2005 (H5N1 virus) strains |
|-----------------|--|

End point description:

Antibody titers were given as GMTs. A/Indonesia/5/2005 = A/INDO and A/Turkey/Turkey/01/2005 = A/TURK.

For D192, antibody titers were tabulated for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protocol.

For D364, antibody titers were tabulated for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 1 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protocol.

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

End point timeframe:

At Days 0, 42, 182, 192, 364

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
|--|--|--|--|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 151 | 147 | 100 | 102 |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/INDO, Day 0 [N=149,145,98,99] | 16.6 (15.4 to 17.9) | 16 (15 to 17) | 15.3 (14.4 to 16.3) | 16 (14.9 to 17.3) |
| A/INDO,Day 42 [N=150,146,99,100] | 726.8 (646.1 to 817.6) | 804.1 (710.8 to 909.5) | 15.3 (14.4 to 16.4) | 17 (15.1 to 19.1) |
| A/INDO, Day 182 [N=151,147,100,102] | 133.3 (125.2 to 142) | 140.7 (132.1 to 149.8) | 15 (14.2 to 15.8) | 14.7 (14 to 15.5) |
| A/INDO, Day 192 [N=149,NA,99,NA] | 2128 (1864 to 2429.5) | 0 (0 to 0) | 38.6 (33.7 to 44.1) | 0 (0 to 0) |
| A/INDO, Day 364 [N=149,147,100,NA] | 523.1 (452.9 to 604.2) | 132.7 (123.9 to 142.2) | 30.4 (26.8 to 34.4) | 0 (0 to 0) |
| A/TURK, Day 0, [N=149,145,98,100] | 16.4 (15.3 to 17.6) | 15.9 (15 to 16.9) | 15.6 (14.5 to 16.8) | 17.3 (15.8 to 19) |
| A/TURK, Day 42, [N=150,146,98,100] | 155.7 (141.9 to 171) | 162.7 (147.8 to 179.2) | 16 (14.7 to 17.5) | 17.6 (15.9 to 19.5) |
| A/TURK, Day 182, [N=151,147,100,101] | 85.3 (79.7 to 91.2) | 85.1 (79.2 to 91.3) | 15.7 (14.6 to 16.8) | 15.5 (14.5 to 16.5) |
| A/TURK, Day 192, [N=150,NA,100,NA] | 1420.4 (1229.6 to 1640.8) | 0 (0 to 0) | 68.3 (58.2 to 80.2) | 0 (0 to 0) |
| A/TURK, Day 364, [N=149,145,98,NA] | 415.2 (359.2 to 479.9) | 99.9 (92.6 to 107.9) | 67.1 (59.6 to 75.5) | 0 (0 to 0) |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related solicited local symptoms.

| | |
|-----------------|--|
| End point title | Number of subjects with any, grade 3 and related solicited local symptoms. |
|-----------------|--|

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 100 millimeters (mm) of injection site. Relationship analysis was not performed.

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

End point timeframe:

During a 7-day (Day 0-6) follow-up period after each vaccination

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
|---|--|---|---|-----------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 156 | 156 | 104 | 104 |
| Units: Subjects | | | | |
| Any Pain, D1 [N=156,156,104,104] | 106 | 112 | 45 | 43 |
| Grade 3 Pain, D1 [N=156,156,104,104] | 2 | 3 | 1 | 1 |
| Any Redness, D1 [N=156,156,104,104] | 0 | 1 | 0 | 1 |
| Grade 3 Redness, D1 [N=156,156,104,104] | 0 | 0 | 0 | 0 |
| Any Swelling, D1 [N=156,156,104,104] | 9 | 9 | 0 | 1 |
| Grade 3 Swelling, D1 [N=156,156,104,104] | 0 | 0 | 0 | 0 |
| Any Pain, D2 [N=156,156,104,103] | 93 | 103 | 65 | 29 |
| Grade 3 Pain, D2 [N=156,156,104,103] | 3 | 0 | 0 | 0 |
| Any Redness, D2 [N=156,156,104,103] | 3 | 1 | 1 | 1 |
| Grade 3 Redness, D2 [N=156,156,104,103] | 0 | 0 | 0 | 0 |
| Any Swelling, D2 [N=156,156,104,103] | 7 | 7 | 2 | 1 |
| Grade 3 Swelling, D2 [N=156,156,104,103] | 0 | 0 | 0 | 0 |
| Any Pain, D3 [N=156,154,0,0] | 105 | 52 | 0 | 0 |
| Grade 3 Pain, D3 [N=156,154,0,0] | 0 | 0 | 0 | 0 |
| Any Redness, D3 [N=156,154,0,0] | 1 | 0 | 0 | 0 |
| Grade 3 Redness, D3 [N=156,154,0,0] | 0 | 0 | 0 | 0 |
| Any Swelling, D3 [N=156,154,0,0] | 4 | 0 | 0 | 0 |
| Grade 3 Swelling, D3 [N=156,154,0,0] | 0 | 0 | 0 | 0 |
| Any Pain, Across [N=156,156,104,104] | 127 | 129 | 73 | 53 |
| Grade 3 Pain, Across [N=156,156,104,104] | 5 | 3 | 1 | 1 |
| Any Redness, Across [N=156,156,104,104] | 4 | 2 | 1 | 1 |
| Grade 3 Redness, Across [N=156,156,104,104] | 0 | 0 | 0 | 0 |
| Any Swelling, Across [N=156,156,104,104] | 15 | 13 | 2 | 1 |
| Grade 3 Swelling, Across [N=156,156,104,104] | 0 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related solicited general symptoms.

| | |
|-----------------|--|
| End point title | Number of subjects with any, grade 3 and related solicited general symptoms. |
|-----------------|--|

End point description:

Assessed solicited general symptoms were diarrhea/vomiting, drowsiness, irritability/fussiness, loss of appetite and temperature [defined as axillary temperature equal to or above 38 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.0 °C. Related = symptom assessed by the investigator as related to the vaccination. The symptoms were assessed for subjects aged less than 6 years.

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

End point timeframe:

During a 7-day (Day 0-6) follow-up period after each vaccination

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
|----------------------------------|--|--|--|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 30 | 31 | 22 | 24 |
| Units: Subjects | | | | |
| Any diarrhoea/vomiting | 2 | 3 | 2 | 0 |
| Grade 3 diarrhoea/vomiting | 0 | 0 | 0 | 0 |
| Related diarrhoea/vomiting | 2 | 3 | 2 | 0 |
| Any drowsiness | 5 | 8 | 3 | 2 |
| Grade 3 drowsiness | 0 | 2 | 0 | 0 |
| Related drowsiness | 5 | 8 | 3 | 2 |
| Any irritability / fussiness | 8 | 10 | 3 | 1 |
| Grade 3 irritability / fussiness | 0 | 0 | 0 | 0 |
| Related irritability / fussiness | 8 | 10 | 3 | 1 |
| Any loss of appetite | 8 | 9 | 3 | 1 |
| Grade 3 loss of appetite | 0 | 0 | 0 | 0 |
| Related loss of appetite | 8 | 8 | 3 | 1 |
| Any temperature | 12 | 11 | 1 | 0 |
| Grade 3 temperature | 2 | 4 | 1 | 0 |
| Related temperature | 11 | 10 | 1 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related solicited general symptoms.

| | |
|-----------------|--|
| End point title | Number of subjects with any, grade 3 and related solicited general symptoms. |
|-----------------|--|

End point description:

Assessed solicited general symptoms were arthralgia, fatigue, gastrointestinal symptoms, headache, myalgia and temperature[defined as axillary temperature equal to or above 38 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.0 °C. Related = symptom assessed by the investigator as related to the vaccination. The symptoms were assessed for subjects aged 6 years or more.

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

End point timeframe:

During a 7-day (Day 0-6) follow-up period after vaccination

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
|---------------------------------------|--|---|---|-----------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 126 | 125 | 82 | 80 |
| Units: Subjects | | | | |
| Any Arthralgia, D1 | 13 | 20 | 7 | 8 |
| Grade 3 Arthralgia, D1 | 0 | 0 | 0 | 0 |
| Related Arthralgia, D1 | 12 | 19 | 7 | 7 |
| Any Fatigue, D1 | 16 | 16 | 8 | 8 |
| Grade 3 Fatigue, D1 | 0 | 0 | 0 | 0 |
| Related Fatigue, D1 | 15 | 16 | 8 | 7 |
| Any Gastrointestinal symptoms, D1 | 9 | 5 | 6 | 7 |
| Grade 3 Gastrointestinal symptoms, D1 | 0 | 0 | 0 | 1 |
| Related Gastrointestinal symptoms, D1 | 7 | 5 | 6 | 6 |
| Any Headache, D1 | 31 | 24 | 14 | 19 |
| Grade 3 Headache, D1 | 1 | 1 | 0 | 0 |
| Related Headache, D1 | 30 | 23 | 12 | 17 |
| Any Myalgia, D1 | 14 | 23 | 8 | 11 |
| Grade 3 Myalgia, D1 | 0 | 0 | 0 | 0 |
| Related Myalgia, D1 | 14 | 22 | 8 | 10 |
| Any Temperature/(Axillary), D1 | 10 | 2 | 6 | 7 |
| Grade 3 Temperature/(Axillary), D1 | 1 | 1 | 2 | 1 |
| Related Temperature/(Axillary), D1 | 8 | 1 | 3 | 5 |
| Any Arthralgia, D2 | 11 | 18 | 5 | 3 |
| Grade 3 Arthralgia, D2 | 0 | 0 | 0 | 0 |
| Related Arthralgia, D2 | 11 | 18 | 5 | 3 |
| Any Fatigue, D2 | 12 | 7 | 5 | 3 |
| Grade 3 Fatigue, D2 | 0 | 0 | 0 | 0 |
| Related Fatigue, D2 | 12 | 7 | 5 | 3 |
| Any Gastrointestinal symptoms, D2 | 6 | 7 | 3 | 1 |
| Grade 3 Gastrointestinal symptoms, D2 | 0 | 0 | 0 | 0 |
| Related Gastrointestinal symptoms, D2 | 6 | 7 | 3 | 1 |
| Any Headache, D2 | 40 | 37 | 8 | 12 |
| Grade 3 Headache, D2 | 4 | 0 | 0 | 1 |
| Related Headache, D2 | 39 | 37 | 8 | 12 |
| Any Myalgia, D2 | 13 | 20 | 7 | 3 |
| Grade 3 Myalgia, D2 | 0 | 0 | 0 | 0 |
| Related Myalgia, D2 | 13 | 19 | 7 | 3 |
| Any Temperature/(Axillary), D2 | 11 | 17 | 4 | 0 |
| Grade 3 Temperature/(Axillary), D2 | 2 | 5 | 0 | 0 |
| Related Temperature/(Axillary), D2 | 0 | 15 | 4 | 0 |
| Any Arthralgia, D3 | 19 | 3 | 0 | 0 |
| Grade 3 Arthralgia, D3 | 0 | 0 | 0 | 0 |
| Related Arthralgia, D3 | 19 | 3 | 0 | 0 |

| | | | | |
|---|----|----|----|----|
| Any Fatigue, D3 | 15 | 8 | 0 | 0 |
| Grade 3 Fatigue, D3 | 0 | 0 | 0 | 0 |
| Related Fatigue, D3 | 15 | 8 | 0 | 0 |
| Any Gastrointestinal symptoms, D3 | 4 | 6 | 0 | 0 |
| Grade 3 Gastrointestinal symptoms, D3 | 0 | 0 | 0 | 0 |
| Related Gastrointestinal symptoms, D3 | 4 | 6 | 0 | 0 |
| Any Headache, D3 | 39 | 17 | 0 | 0 |
| Grade 3 Headache, D3 | 1 | 0 | 0 | 0 |
| Related Headache, D3 | 39 | 17 | 0 | 0 |
| Any Myalgia, D3 | 15 | 2 | 0 | 0 |
| Grade 3 Myalgia, D3 | 0 | 0 | 0 | 0 |
| Related Myalgia, D3 | 15 | 2 | 0 | 0 |
| Any Temperature/(Axillary), D3 | 7 | 2 | 0 | 0 |
| Grade 3 Temperature/(Axillary), D3 | 0 | 0 | 0 | 0 |
| Related Temperature/(Axillary), D3 | 7 | 2 | 0 | 0 |
| Any Arthralgia, Across | 33 | 31 | 11 | 11 |
| Grade 3 Arthralgia, Across | 0 | 0 | 0 | 0 |
| Related Arthralgia, Across | 32 | 30 | 11 | 10 |
| Any Fatigue, Across | 28 | 22 | 10 | 10 |
| Grade 3 Fatigue, Across | 0 | 0 | 0 | 0 |
| Related Fatigue, Across | 28 | 22 | 10 | 9 |
| Any Gastrointestinal symptoms, Across | 16 | 12 | 8 | 7 |
| Grade 3 Gastrointestinal symptoms, Across | 0 | 0 | 0 | 1 |
| Related Gastrointestinal symptoms, Across | 15 | 12 | 8 | 6 |
| Any Headache, Across | 63 | 52 | 20 | 24 |
| Grade 3 Headache, Across | 5 | 1 | 0 | 1 |
| Related Headache, Across | 62 | 51 | 18 | 22 |
| Any Myalgia, Across | 29 | 33 | 13 | 13 |
| Grade 3 Myalgia, Across | 0 | 0 | 0 | 0 |
| Related Myalgia, Across | 29 | 31 | 13 | 12 |
| Any Temperature/(Axillary), Across | 23 | 19 | 10 | 7 |
| Grade 3 Temperature/(Axillary), Across | 3 | 6 | 2 | 1 |
| Related Temperature/(Axillary), Across | 20 | 16 | 7 | 5 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related unsolicited adverse events (AEs).

| | |
|-----------------|--|
| End point title | Number of subjects with any, grade 3 and related unsolicited adverse events (AEs). |
|-----------------|--|

End point description:

An unsolicited AE covers 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 and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities. Related = AE assessed by the investigator as related to the vaccination.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| During a 21-day (Days 0 – 20) follow-up period after vaccination | |

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
|-----------------------------|--|--|--|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 156 | 156 | 104 | 104 |
| Units: Subjects | | | | |
| Any AEs | 60 | 82 | 35 | 20 |
| Grade 3 AEs | 1 | 1 | 0 | 0 |
| Related AEs | 12 | 7 | 7 | 3 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related unsolicited adverse events (AEs).

| | |
|-----------------|--|
| End point title | Number of subjects with any, grade 3 and related unsolicited adverse events (AEs). |
|-----------------|--|

End point description:

An unsolicited AE covers 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 and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities. Related = AE assessed by the investigator as related to the vaccination.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| During Day 0 to Telephone Contact (TC) Day 84 overall. | |

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
|-----------------------------|--|--|--|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 156 | 156 | 104 | 104 |
| Units: Subjects | | | | |
| Any AEs | 75 | 92 | 59 | 50 |
| Grade 3 AEs | 2 | 0 | 1 | 1 |
| Related AEs | 7 | 6 | 3 | 3 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any potential Immune-Mediated Diseases (pIMDs)

| | |
|-----------------|--|
| End point title | Number of subjects with any potential Immune-Mediated Diseases (pIMDs) |
|-----------------|--|

End point description:

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

End point timeframe:

During the entire study period (Day 0 to 364)

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
|-----------------------------|--|--|--|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 156 | 156 | 104 | 104 |
| Units: Subjects | | | | |
| Any pIMDs | 0 | 0 | 0 | 0 |

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). |
|-----------------|--|

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:

During the entire study period (Day 0 to 364)

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
|-----------------------------|--|--|--|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 156 | 156 | 104 | 104 |
| Units: Subjects | | | | |
| (SAEs). | 4 | 1 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-H5N1 antibodies above the cut off values $\geq 1:10$

| | |
|-----------------|---|
| End point title | Number of subjects with anti-H5N1 antibodies above the cut off values $\geq 1:10$ |
|-----------------|---|

End point description:

Seropositivity rates against the A/Indonesia/5/2005 (H5N1 virus) strain, were tabulated 95% CI on Days 0,42,182 for all subjects, 192 for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and 364 for GSK1562902A Formulation 1 - Havrix / Havrix Jr Group. Seropositivity rates against the A/turkey/Turkey/01/2005 (H5N1 virus) strain, were tabulated 95% CI on Days 182, 192 and 364.

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

End point timeframe:

At Days 0, 42, 182, 192 and 364

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
|-------------------------------------|--|--|--|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 155 | 152 | 103 | 101 |
| Units: Subjects | | | | |
| A/INDO, Day 0 [N=155,152,103,101] | 22 | 15 | 8 | 14 |
| A/INDO, Day 42 [N=155,152,103,101] | 155 | 151 | 9 | 19 |
| A/INDO, Day 182 [N=155,152,103,101] | 154 | 152 | 2 | 12 |
| A/INDO, Day 192 [N=127,0,45,0] | 127 | 0 | 37 | 0 |
| A/INDO, Day 364 [N=151,147,100,0] | 151 | 147 | 57 | 0 |
| A/TURK, Day 182 [N=127,152,84,101] | 126 | 152 | 17 | 26 |
| A/TURK, Day 364 [N=151,147,100,0] | 151 | 147 | 95 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroconverted subjects against the A/Indonesia/05/2005 strains of H5N1 influenza disease

| | |
|-----------------|--|
| End point title | Number of seroconverted subjects against the A/Indonesia/05/2005 strains of H5N1 influenza disease |
|-----------------|--|

End point description:

Seroconversion rates against the A/Indonesia/05/2005 (H5N1 VIRUS) strain were tabulated 95% CI on Days 0,42,182 for all subjects, 192 for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and 364 for GSK1562902A Formulation 1 - Havrix / Havrix Jr Group and GSK1562902A Formulation 1 - Havrix / Havrix Jr Group.

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

End point timeframe:

At Days 42, 182, 192 and 364

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
|-------------------------------------|--|--|--|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 155 | 152 | 103 | 101 |
| Units: Subjects | | | | |
| A/INDO, Day 42 [N=155,152,103,101] | 154 | 151 | 1 | 1 |
| A/INDO, Day 182 [N=155,152,103,101] | 122 | 121 | 0 | 0 |
| A/INDO, Day 192 [N=127,0,84,0] | 127 | 0 | 3 | 0 |
| A/INDO, Day 364 [N=151,147,100,0] | 151 | 100 | 1 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against the A/Indonesia/05/2005 and A/turkey/Turkey/01/2005 strains of H5N1 influenza disease

| | |
|-----------------|--|
| End point title | Number of seroprotected subjects against the A/Indonesia/05/2005 and A/turkey/Turkey/01/2005 strains of H5N1 influenza disease |
|-----------------|--|

End point description:

Seroprotection rates against the A/Indonesia/5/2005 (H5N1 virus) strain, were tabulated 95% CI on Days 0,42,182 for all subjects, 192 for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and 364 for GSK1562902A Formulation 1 - Havrix / Havrix Jr Group and GSK1562902A Formulation 1 - Havrix / Havrix Jr Group. Seroprotection rates against the A/turkey/Turkey/01/2005 (H5N1 virus) strain, were tabulated 95% CI on Days 182 and 192.

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

End point timeframe:

At Days 0,42, 182, 192 and 364

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
|-------------------------------------|--|--|--|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 155 | 152 | 103 | 101 |
| Units: Subjects | | | | |
| A/INDO, Day 0 [N=155,152,103,101] | 0 | 0 | 2 | 1 |
| A/INDO, Day 42 [N=155,152,103,101] | 154 | 151 | 2 | 1 |
| A/INDO, Day 182 [N=155,152,103,101] | 125 | 122 | 0 | 0 |
| A/INDO, Day 192 [N=127,0,84,0] | 127 | 0 | 3 | 0 |
| A/INDO, Day 364 [N=151,147,100,0] | 151 | 102 | 1 | 0 |
| A/TURK, Day 182 [N=127,0,84,0] | 73 | 0 | 1 | 0 |
| A/TURK, Day 192 [N=127,0,84,0] | 127 | 0 | 28 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean geometric increase for anti-H5N1 antibody titers

| | |
|---|---|
| End point title | Mean geometric increase for anti-H5N1 antibody titers |
| End point description: | |
| MGI against the A/Indonesia/05/2005 (H5N1 VIRUS) strain were tabulated on Days 0,42,182 for all subjects, 192 for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and 364 for GSK1562902A Formulation 1 - Havrix / Havrix Jr Group and GSK1562902A Formulation 1 - Havrix / Havrix Jr Group. MGI against the A/turkey/Turkey/01/2005 (H5N1 virus) strain were tabulated on Days 42, 182 and 364. | |
| End point type | Secondary |
| End point timeframe: | |
| At Days 42, 182, 192 and 364 | |

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
|--|--|--|--|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 155 | 152 | 103 | 101 |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/INDO, Day 42 [N=155,152,103,101] | 96.9 (84.9 to 110.4) | 108.4 (94.2 to 124.7) | 1 (1 to 1.1) | 1.1 (0.9 to 1.2) |
| A/INDO, Day 182 [N=155,152,103,101] | 9.1 (8.3 to 10.1) | 9.8 (9 to 10.8) | 0.9 (0.9 to 1) | 1 (0.9 to 1.1) |
| A/INDO, Day 192 [N=127,0,84,0] | 117.7 (103 to 134.5) | 0 (0 to 0) | 1.4 (1.2 to 1.6) | 0 (0 to 0) |
| A/INDO, Day 364 [N=151,147,100,0] | 36.2 (32 to 40.9) | 7.4 (6.7 to 8.2) | 1.6 (1.4 to 1.7) | 0 (0 to 0) |
| A/TURK, Day 42 [N=155,152,103,101] | 27.7 (24 to 31.9) | 33.1 (28.6 to 38.3) | 1.1 (1 to 1.3) | 1.2 (1.1 to 1.3) |

| | | | | |
|-------------------------------------|---------------------|----------------|----------------|----------------|
| A/TURK, Day 182 [N=155,152,103,101] | 5.6 (5 to 6.3) | 6.6 (6 to 7.4) | 1 (0.9 to 1.1) | 1 (0.9 to 1.1) |
| A/TURK, Day 364 [N=151,147,100,0] | 31.4 (26.9 to 36.7) | 5.6 (5 to 6.3) | 3 (2.6 to 3.4) | 0 (0 to 0) |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroconverted subjects against the A/turkey/Turkey/01/2005 strains of H5N1 influenza disease

| | |
|-----------------|---|
| End point title | Number of seroconverted subjects against the A/turkey/Turkey/01/2005 strains of H5N1 influenza disease ^[5] |
|-----------------|---|

End point description:

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

End point timeframe:

At Days 192 and 364

Notes:

[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: The analysis was made only on subjects receiving A/turkey/Turkey/01/2005 strain containing vaccine.

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | | |
|---------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 151 | 100 | | |
| Units: Subjects | | | | |
| A/TURK, Day 192 [N=127,0,84,0] | 127 | 27 | | |
| A/TURK, Day 364 [N=151,0,100,0] | 105 | 18 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Booster factor for Hemagglutination Inhibition (HI) antibodies against the A/turkey/Turkey/01/2005 strain of H5N1 influenza disease

| | |
|-----------------|--|
| End point title | Booster factor for Hemagglutination Inhibition (HI) antibodies against the A/turkey/Turkey/01/2005 strain of H5N1 influenza disease ^[6] |
|-----------------|--|

End point description:

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

End point timeframe:

At Days 192 and 364

Notes:

[6] - 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: The analysis was made only on subjects receiving A/turkey/Turkey/01/2005 strain containing vaccine.

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | | |
|--|--|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 151 | 100 | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| A/TURK, Day 192 [N=127,0,84,0] | 18.6 (16.3 to 21.3) | 4.1 (3.3 to 5.2) | | |
| A/TURK, Day 364 [N=151,0,100,0] | 5.6 (5 to 6.3) | 3 (2.7 to 3.4) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with neutralizing anti-H5N1 antibody titers

| | |
|-----------------|--|
| End point title | Number of subjects with neutralizing anti-H5N1 antibody titers |
|-----------------|--|

End point description:

Seropositivity rates against the A/Indonesia/5/2005 (H5N1 virus) strain, were tabulated 95 % CI on Days 0,42,182 for all subjects, 192 for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 2 - Havrix / Havrix Jr Group and 364 for GSK1562902A Formulation 1 - Havrix / Havrix Jr Group and GSK1562902A Formulation 1 - Havrix / Havrix Jr Group. Seropositivity rates against the A/turkey/Turkey/01/2005 (H5N1 virus) strain, were tabulated 95% CI on Days 0, 42,182, 192 and 364.

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

End point timeframe:

At Days 0, 42, 182 192 and 364

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
|-------------------------------------|--|--|--|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 151 | 147 | 100 | 102 |
| Units: Subjects | | | | |
| A/INDO, Day 0 [N=149,145,98,99] | 22 | 17 | 8 | 14 |
| A/INDO,Day 42 [N=150,146,99,100] | 150 | 146 | 9 | 15 |
| A/INDO, Day 182 [N=151,147,100,102] | 150 | 147 | 7 | 4 |
| A/INDO, Day 192 [N=149,0,99,0] | 149 | 0 | 75 | 0 |
| A/INDO, Day 364 [N=149,147,100,0] | 149 | 147 | 73 | 0 |
| A/TURK, Day 0, [N=149,145,98,100] | 21 | 18 | 8 | 19 |

| | | | | |
|---|-----|-----|----|----|
| A/TURK, Day 42, [N=150,146,98,100] | 150 | 145 | 10 | 20 |
| A/TURK, Day 182, [N=151,147,100,101] | 150 | 145 | 11 | 10 |
| A/TURK, Day 192, [N=150,0,100,0] | 150 | 0 | 90 | 0 |
| A/TURK, Day 364, [N=149,145,98,0] | 149 | 145 | 95 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with vaccine response rates (VRR) for H5N1 neutralizing antibodies

| | |
|--|---|
| End point title | Number of subjects with vaccine response rates (VRR) for H5N1 neutralizing antibodies |
| End point description: | |
| VRR was defined as the number of vaccinees who have at least a 4-fold increase in post-vaccination titre relative to pre-vaccination titre (Day 0). For D192 , antibody titers were tabulated for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protocol. For D364, antibody titers were tabulated for GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group, GSK1562902A Formulation 1 - Havrix / Havrix Jr Group and GSK1562902A Formulation 2 - Havrix / Havrix Jr Group as required by the protocol. | |
| End point type | Secondary |
| End point timeframe: | |
| At Days 42, 182 192 and 364 | |

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | Havrix / Havrix Jr Group |
|-----------------------------------|--|--|--|--------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 149 | 145 | 98 | 98 |
| Units: Subjects | | | | |
| A/INDO,Day 42 [N=149,144,98,98] | 147 | 142 | 0 | 2 |
| A/INDO, Day 182 [N=149,145,98,98] | 127 | 115 | 0 | 0 |
| A/INDO, Day 192 [N=147,0,97,0] | 147 | 0 | 5 | 0 |
| A/INDO, Day 364 [N=148,145,98,0] | 144 | 126 | 8 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with booster vaccine response for H5N1 neutralizing antibodies

| | |
|-----------------|--|
| End point title | Number of subjects with booster vaccine response for H5N1 neutralizing antibodies ^[7] |
|-----------------|--|

End point description:

Booster VRR was defined as the number of vaccinees with at least a 4-fold increase in post-booster vaccination titre relative to pre-booster vaccination (Day 182).

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

End point timeframe:

At Days 192 and 364

Notes:

[7] - 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: The analysis was made only on subjects receiving A/turkey/Turkey/01/2005 strain containing vaccine.

| End point values | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group | | |
|----------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 150 | 100 | | |
| Units: Subjects | | | | |
| A/TURK, Day 192, [N=150,0,100,0] | 141 | 38 | | |
| A/TURK, Day 364, [N=149,0,98,0] | 86 | 36 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Systematically-assessed symptoms: during the 7 days after each vaccination; unsolicited AEs: within 21 days after each vaccination and from Day 0 to Day 84. SAEs were collected throughout the study from Day 0 to Day 364.

Adverse event reporting additional description:

Solicited general symptoms were assessed in subjects aged less than 6 years and in subjects aged 6 years and more as required by the protocol.

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 15.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--|
| Reporting group title | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group |
|-----------------------|--|

Reporting group description:

Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1, a booster vaccination dose of Influenza vaccine GSK1562902A Formulation 2 and 1 dose of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

| | |
|-----------------------|--|
| Reporting group title | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group |
|-----------------------|--|

Reporting group description:

Subjects in this group received 2 primary vaccination doses of Influenza vaccine GSK1562902A Formulation 1 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

| | |
|-----------------------|--|
| Reporting group title | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group |
|-----------------------|--|

Reporting group description:

Subjects in this group received 1 dose of Influenza vaccine GSK1562902A Formulation 2 and 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

| | |
|-----------------------|--------------------------|
| Reporting group title | Havrix / Havrix Jr Group |
|-----------------------|--------------------------|

Reporting group description:

Subjects in this group received 2 doses of Havrix™ or Havrix™ Junior vaccine, administered intramuscularly in the deltoid region.

| Serious adverse events | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group |
|---|--|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 4 / 156 (2.56%) | 1 / 156 (0.64%) | 0 / 104 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Open wound | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 156 (0.64%) | 0 / 104 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 156 (0.00%) | 0 / 104 (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 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 156 (0.00%) | 0 / 104 (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 |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 156 (0.00%) | 0 / 104 (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 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 156 (0.00%) | 0 / 104 (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 |
| Typhoid fever | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 156 (0.00%) | 0 / 104 (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 |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 156 (0.00%) | 0 / 104 (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 | Havrix / Havrix Jr Group | | |
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 104 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Injury, poisoning and procedural complications | | | |
| Open wound | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 104 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 0 / 104 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 104 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 104 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 104 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Typhoid fever | | | |
| subjects affected / exposed | 0 / 104 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 104 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| Non-serious adverse events | GSK1562902A Formulation 1 and 2 - Havrix / Havrix Jr Group | GSK1562902A Formulation 1 - Havrix / Havrix Jr Group | GSK1562902A Formulation 2 - Havrix / Havrix Jr Group |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 127 / 156 (81.41%) | 129 / 156 (82.69%) | 73 / 104 (70.19%) |
| General disorders and administration site conditions | | | |
| Pain | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 127 / 156 (81.41%) | 129 / 156 (82.69%) | 73 / 104 (70.19%) |
| occurrences (all) | 127 | 129 | 73 |
| Swelling | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 15 / 156 (9.62%) | 13 / 156 (8.33%) | 2 / 104 (1.92%) |
| occurrences (all) | 15 | 13 | 2 |
| Diarrhoea/vomiting | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[1] | 2 / 30 (6.67%) | 3 / 31 (9.68%) | 2 / 22 (9.09%) |
| occurrences (all) | 2 | 3 | 3 |
| Drowsiness | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[2] | 5 / 30 (16.67%) | 8 / 31 (25.81%) | 3 / 22 (13.64%) |
| occurrences (all) | 5 | 8 | 3 |
| Irritability / fussiness | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[3] | 8 / 30 (26.67%) | 10 / 31 (32.26%) | 3 / 22 (13.64%) |
| occurrences (all) | 8 | 10 | 3 |
| Loss of appetite | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[4] | 8 / 30 (26.67%) | 9 / 31 (29.03%) | 3 / 22 (13.64%) |
| occurrences (all) | 8 | 9 | 3 |
| Temperature (subjects aged less than 6 years) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[5] | 12 / 30 (40.00%) | 11 / 31 (35.48%) | 1 / 22 (4.55%) |
| occurrences (all) | 12 | 11 | 1 |
| Arthralgia | | | |

| | | | |
|--|------------------------------------|------------------------------------|-----------------------------------|
| <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[6]</p> <p>occurrences (all)</p> | <p>33 / 126 (26.19%)</p> <p>33</p> | <p>31 / 125 (24.80%)</p> <p>31</p> | <p>11 / 82 (13.41%)</p> <p>11</p> |
| <p>Fatigue</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[7]</p> <p>occurrences (all)</p> | <p>28 / 126 (22.22%)</p> <p>28</p> | <p>22 / 125 (17.60%)</p> <p>22</p> | <p>10 / 82 (12.20%)</p> <p>10</p> |
| <p>Gastrointestinal symptoms</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[8]</p> <p>occurrences (all)</p> | <p>16 / 126 (12.70%)</p> <p>16</p> | <p>12 / 125 (9.60%)</p> <p>12</p> | <p>8 / 82 (9.76%)</p> <p>8</p> |
| <p>Headache</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[9]</p> <p>occurrences (all)</p> | <p>63 / 126 (50.00%)</p> <p>63</p> | <p>52 / 125 (41.60%)</p> <p>52</p> | <p>20 / 82 (24.39%)</p> <p>20</p> |
| <p>Myalgia</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[10]</p> <p>occurrences (all)</p> | <p>29 / 126 (23.02%)</p> <p>29</p> | <p>33 / 125 (26.40%)</p> <p>33</p> | <p>13 / 82 (15.85%)</p> <p>13</p> |
| <p>Temperature (subjects aged 6 years or more)</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[11]</p> <p>occurrences (all)</p> | <p>23 / 126 (18.25%)</p> <p>23</p> | <p>19 / 125 (15.20%)</p> <p>19</p> | <p>10 / 82 (12.20%)</p> <p>10</p> |
| <p>Infections and infestations</p> <p>Upper respiratory tract infection (within 21 days post-vaccination)</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>31 / 156 (19.87%)</p> <p>31</p> | <p>54 / 156 (34.62%)</p> <p>54</p> | <p>9 / 104 (8.65%)</p> <p>9</p> |
| <p>Viral infection (within 21 days post- vaccination)</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>2 / 156 (1.28%)</p> <p>2</p> | <p>10 / 156 (6.41%)</p> <p>10</p> | <p>7 / 104 (6.73%)</p> <p>7</p> |
| <p>Rhinitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>5 / 156 (3.21%)</p> <p>5</p> | <p>5 / 156 (3.21%)</p> <p>5</p> | <p>6 / 104 (5.77%)</p> <p>6</p> |
| <p>Upper respiratory tract infection</p> | | | |

| | | | |
|---|-------------------|-------------------|-------------------|
| (Day 0 up to Day 84 post-vaccination) | | | |
| subjects affected / exposed | 45 / 156 (28.85%) | 63 / 156 (40.38%) | 31 / 104 (29.81%) |
| occurrences (all) | 45 | 63 | 31 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 3 / 156 (1.92%) | 8 / 156 (5.13%) | 3 / 104 (2.88%) |
| occurrences (all) | 3 | 8 | 3 |
| Viral infection (Day 0 up to Day 84 post-vaccination) | | | |
| subjects affected / exposed | 10 / 156 (6.41%) | 20 / 156 (12.82%) | 18 / 104 (17.31%) |
| occurrences (all) | 10 | 20 | 18 |

| Non-serious adverse events | Havrix / Havrix Jr Group | | |
|---|--------------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 53 / 104 (50.96%) | | |
| General disorders and administration site conditions | | | |
| Pain | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 53 / 104 (50.96%) | | |
| occurrences (all) | 53 | | |
| Swelling | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 104 (0.96%) | | |
| occurrences (all) | 1 | | |
| Diarrhoea/vomiting | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[1] | 0 / 24 (0.00%) | | |
| occurrences (all) | 0 | | |
| Drowsiness | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[2] | 2 / 24 (8.33%) | | |
| occurrences (all) | 2 | | |
| Irritability / fussiness | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[3] | 1 / 24 (4.17%) | | |
| occurrences (all) | 1 | | |

| | | | |
|--|------------------------|--|--|
| Loss of appetite alternative assessment type: Systematic subjects affected / exposed ^[4] occurrences (all) | 1 / 24 (4.17%) 1 | | |
| Temperature (subjects aged less than 6 years) alternative assessment type: Systematic subjects affected / exposed ^[5] occurrences (all) | 0 / 24 (0.00%) 0 | | |
| Arthralgia alternative assessment type: Systematic subjects affected / exposed ^[6] occurrences (all) | 11 / 80 (13.75%) 11 | | |
| Fatigue alternative assessment type: Systematic subjects affected / exposed ^[7] occurrences (all) | 10 / 80 (12.50%) 10 | | |
| Gastrointestinal symptoms alternative assessment type: Systematic subjects affected / exposed ^[8] occurrences (all) | 7 / 80 (8.75%) 7 | | |
| Headache alternative assessment type: Systematic subjects affected / exposed ^[9] occurrences (all) | 24 / 80 (30.00%) 24 | | |
| Myalgia alternative assessment type: Systematic subjects affected / exposed ^[10] occurrences (all) | 13 / 80 (16.25%) 13 | | |
| Temperature (subjects aged 6 years or more) alternative assessment type: Systematic subjects affected / exposed ^[11] occurrences (all) | 7 / 80 (8.75%) 7 | | |
| Infections and infestations | | | |

| | | | |
|--|-------------------|--|--|
| Upper respiratory tract infection (within 21 days post-vaccination) | | | |
| subjects affected / exposed | 9 / 104 (8.65%) | | |
| occurrences (all) | 9 | | |
| Viral infection (within 21 days post-vaccination) | | | |
| subjects affected / exposed | 2 / 104 (1.92%) | | |
| occurrences (all) | 2 | | |
| Rhinitis | | | |
| subjects affected / exposed | 2 / 104 (1.92%) | | |
| occurrences (all) | 2 | | |
| Upper respiratory tract infection (Day 0 up to Day 84 post-vaccination) | | | |
| subjects affected / exposed | 27 / 104 (25.96%) | | |
| occurrences (all) | 27 | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 6 / 104 (5.77%) | | |
| occurrences (all) | 6 | | |
| Viral infection (Day 0 up to Day 84 post-vaccination) | | | |
| subjects affected / exposed | 10 / 104 (9.62%) | | |
| occurrences (all) | 10 | | |

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: The analysis was performed on the Total vaccinated cohort, only 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: The analysis was performed on the Total vaccinated cohort, only 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: The analysis was performed on the Total vaccinated cohort, only 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: The analysis was performed on the Total vaccinated cohort, only 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: The analysis was performed on the Total vaccinated cohort, only 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: The analysis was performed on the Total vaccinated cohort, only 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

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[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.

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[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: The analysis was performed on the Total vaccinated cohort, only 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: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[11] - 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: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported