



Clinical trial results:

A Phase IIIb, open-label, multi-centric study to evaluate the immunogenicity of one dose of GSK Biologicals' MenACWY-TT conjugate vaccine administered intramuscularly in healthy adolescents aged 10 to 15 years, previously primed with a MenC conjugate vaccine.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2013-004778-84 |
| Trial protocol | SE ES |
| Global end of trial date | 18 June 2014 |

Results information

| | |
|-----------------------------------|---|
| Result version number | v1 (current) |
| This version publication date | 23 December 2018 |
| First version publication date | 23 December 2018 |
| Summary attachment (see zip file) | Cancelled before active statement (Cancelled before Active Statement.pdf) |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 116775 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | - |
| 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, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com |
| Scientific contact | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 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 | 18 June 2014 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|--------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 18 June 2014 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the vaccine response induced by one dose of MenACWY-TT administered to MenC-primed and MenC unprimed subjects.

Protection of trial subjects:

The study was cancelled before active (see attached statement). No patient entered the study, therefore no results / data are available.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 18 June 2014 |
| 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 | Spain: 49999 |
| Country: Number of subjects enrolled | Sweden: 50000 |
| Worldwide total number of subjects | 99999 |
| EEA total number of subjects | 99999 |

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) | 50000 |
| Adolescents (12-17 years) | 49999 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants, the study was cancelled before active. No patient entered the study, therefore no results / data are available.

Pre-assignment

Screening details:

Study cancelled before active (see attached statement)

Period 1

| | |
|------------------------------|---|
| Period 1 title | Cancelled before active period (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Blinding implementation details:

Not blinded

Arms

| | |
|-----------|--------|
| Arm title | No-Arm |
|-----------|--------|

Arm description: -

| | |
|--|--|
| Arm type | cancelled before active |
| Investigational medicinal product name | study cancelled before active |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution and suspension for suspension for injection in pre-filled syringe |
| Routes of administration | Route of administration not applicable |

Dosage and administration details:

cancelled before active

| | |
|---------------------------------------|--------|
| Number of subjects in period 1 | No-Arm |
| Started | 99999 |
| Completed | 0 |
| Not completed | 99999 |
| study was cancelled before active | 99999 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|--------------------------------|
| Reporting group title | Cancelled before active period |
|-----------------------|--------------------------------|

Reporting group description: -

| Reporting group values | Cancelled before active period | Total | |
|------------------------|--------------------------------|-------|--|
| Number of subjects | 99999 | 99999 | |
| Age categorical | | | |
| Units: Subjects | | | |
| Adolescents | 99999 | 99999 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 50000 | 50000 | |
| Male | 49999 | 49999 | |

End points

End points reporting groups

| | |
|--------------------------------|--------|
| Reporting group title | No-Arm |
| Reporting group description: - | |

Primary: No endpoint results

| | |
|------------------------|------------------------------------|
| End point title | No endpoint results ^[1] |
| End point description: | |

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

End point timeframe:

The study was cancelled before active (see attached statement)

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 study was cancelled before active (see attached statement).

| | | | | |
|-----------------------------|-----------------|--|--|--|
| End point values | No-Arm | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 99999 | | | |
| Units: Participants | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

The study was cancelled before active (see attached statement)

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 18.1 |
|--------------------|------|

Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: The study was cancelled before active (see attached statement).

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? Yes

| Date | Interruption | Restart date |
|--------------|---|--------------|
| 18 June 2014 | The study was cancelled before active (see attached statement). | - |

Notes:

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

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|---------------|
| None reported |
|---------------|

Notes: