



Clinical trial results:

A phase II, open-label, randomised, multicentre study to evaluate the safety and immunogenicity of GlaxoSmithKline Biologicals' DTPa-HBV-IPV/Hib-MenC-TT vaccine, when given in healthy infants at 3, 5 and 11 months of age.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2008-006365-91 |
| Trial protocol | SK |
| Global end of trial date | 25 June 2009 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 |
| This version publication date | 20 November 2018 |
| First version publication date | 04 June 2015 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 111761 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00871741 |
| 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, 044 2089-904466, GSKClinicalSupportHD@gsk.com |
| Scientific contact | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, 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 | 26 May 2009 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 26 May 2009 |
| Global end of trial reached? | Yes |
| Global end of trial date | 25 June 2009 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

- To demonstrate that GSK Biologicals' DTPa-HBV-IPV/Hib-MenC-TT vaccine (Combo group) is non-inferior to GSK Biologicals' DTPa-HBV-IPV/Hib (Infanrix hexa) vaccine co-administered with Novartis' meningococcal serogroup C vaccine (Menjugate) (Control group), in terms of immune response to Hib and MenC antigens, one month after the second vaccine dose.

Criteria for non-inferiority:

Non-inferiority in terms of response to PRP will be demonstrated if the upper limit of the standardized asymptotic 95% confidence interval (CI) on the group difference [Control minus Combo] in percentage of subjects with anti-PRP antibody concentrations $\geq 0.15 \mu\text{g/ml}$ is $\leq 10\%$.

Non-inferiority in terms of response to MenC will be demonstrated if the upper limit of the standardized asymptotic 95% CI on the group difference [Control minus Combo] in percentage of subjects with rSBA-MenC titres ≥ 8 is $\leq 10\%$.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

| | |
|-----------------------------------------------------------|---------------|
| Actual start date of recruitment | 06 April 2009 |
| 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 | Slovakia: 16 |
| Worldwide total number of subjects | 16 |
| EEA total number of subjects | 16 |

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) | 16 |
| 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:

The number of actual participants that completed is 0 (due to study termination no subjects completed the study), however due to a system constraint (0 in an invalid value), the value of 7 and respectively 9 has been entered in the Completed field.

Pre-assignment

Screening details:

During the screening the following steps occurred: check for inclusion/exclusion criteria, contraindications/precautions, medical history of the subjects and signing informed consent forms.

Pre-assignment period milestones

| | |
|------------------------------|----|
| Number of subjects started | 16 |
| Number of subjects completed | 16 |

Period 1

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

Arms

| | |
|------------------------------|-------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Combo Group |

Arm description:

Subjects in this group were to receive three doses of GSK2202083A vaccine at 3, 5 and 11 months of age.

| | |
|----------------------------------------|---------------------|
| Arm type | Experimental |
| Investigational medicinal product name | GSK2202083A vaccine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Intramuscular injection in the anterolateral quadrant of the right thigh, three doses at 3, 5 and 11 months of age.

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

Arm description:

Subjects in this group were to receive three doses of Infanrix™ hexa vaccine at 3, 5 and 11 months of age, and two doses of Menjugate vaccine at 3 and 5 months of age.

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

Dosage and administration details:

Intramuscular injection in the left anterolateral thigh, three doses at 3, 5 and 11 months of age.

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

Dosage and administration details:

Intramuscular injection in the right anterolateral thigh, 2 doses at 3 and 5 months of age.

| Number of subjects in period 1 | Combo Group | Control Group |
|---------------------------------------|------------------|------------------|
| Started | 9 | 7 |
| Vaccinated | 0 ^[1] | 0 ^[2] |
| Completed | 9 | 7 |

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The study was terminated before the subjects were vaccinated.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The study was terminated before the subjects were vaccinated.

Baseline characteristics

Reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | Combo Group |
|-----------------------|-------------|

Reporting group description:

Subjects in this group were to receive three doses of GSK2202083A vaccine at 3, 5 and 11 months of age.

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

Reporting group description:

Subjects in this group were to receive three doses of Infanrix™ hexa vaccine at 3, 5 and 11 months of age, and two doses of Menjugate vaccine at 3 and 5 months of age.

| Reporting group values | Combo Group | Control Group | Total |
|----------------------------------------------------|-------------|---------------|-------|
| Number of subjects | 9 | 7 | 16 |
| 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: weeks | | | |
| arithmetic mean | 12.8 | 13.9 | |
| standard deviation | ± 2.28 | ± 1.57 | - |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 2 | 5 | 7 |
| Male | 7 | 2 | 9 |

End points

End points reporting groups

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| Reporting group title | Combo Group |
| Reporting group description: Subjects in this group were to receive three doses of GSK2202083A vaccine at 3, 5 and 11 months of age. | |
| Reporting group title | Control Group |
| Reporting group description: Subjects in this group were to receive three doses of Infanrix™ hexa vaccine at 3, 5 and 11 months of age, and two doses of Menjugate vaccine at 3 and 5 months of age. | |

Primary: Anti- PRP antibody concentrations ≥ 0.15 mg/mL.

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| End point title | Anti- PRP antibody concentrations ≥ 0.15 mg/mL. ^[1] |
| End point description: | |
| End point type | Primary |
| End point timeframe: One Month after the second vaccine dose | |
| 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. | |

| End point values | Combo Group | Control Group | | |
|-----------------------------|------------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[2] | 0 ^[3] | | |
| Units: Subjects | | | | |
| Anti-PRP | | | | |

Notes:

[2] - As the study was terminated, no blood samples were taken. Hence no immunogenicity analyses were done

[3] - As the study was terminated, no blood samples were taken. Hence no immunogenicity analyses were done

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related solicited local symptoms for Dose 1

| | |
|--------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| End point title | Number of subjects with any, grade 3 and related solicited local symptoms for Dose 1 |
| End point description: The solicited local symptoms assessed were pain, redness and swelling. | |
| End point type | Secondary |
| End point timeframe: During the 8-day (Days 0-7) post-vaccination period | |

| End point values | Combo Group | Control Group | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9 | 7 | | |
| Units: Subjects | | | | |
| Any pain | 2 | 2 | | |
| Grade 3 pain | 0 | 0 | | |
| Any redness | 4 | 4 | | |
| Grade 3 redness | 0 | 0 | | |
| Any swelling | 3 | 1 | | |
| Grade 3 swelling | 1 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related solicited local symptoms for Dose 2.

| | |
|-----------------|------------------------------------------------------------------------------------------------------|
| End point title | Number of subjects with any, grade 3 and related solicited local symptoms for Dose 2. ^[4] |
|-----------------|------------------------------------------------------------------------------------------------------|

End point description:

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

End point timeframe:

During the 8-day (Days 0-7) post-vaccination period

Notes:

[4] - 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: No subjects from the Control Group had received the second dose of vaccine due to study termination.

| End point values | Combo Group | | | |
|-----------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 1 | | | |
| Units: Subjects | | | | |
| Any pain | 0 | | | |
| Grade 3 pain | 0 | | | |
| Any redness | 0 | | | |
| Grade 3 redness | 0 | | | |
| Any swelling | 0 | | | |
| Grade 3 swelling | 0 | | | |

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

End point timeframe:

During the 8-day (Days 0-7) post-vaccination period

| End point values | Combo Group | Control Group | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9 | 7 | | |
| Units: Subjects | | | | |
| Any pain | 2 | 2 | | |
| Grade 3 pain | 0 | 0 | | |
| Any redness | 4 | 4 | | |
| Grade 3 redness | 0 | 0 | | |
| Any swelling | 3 | 1 | | |
| Grade 3 swelling | 1 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related solicited general symptoms for Dose 1

| | |
|-----------------|----------------------------------------------------------------------------------------|
| End point title | Number of subjects with any, grade 3 and related solicited general symptoms for Dose 1 |
|-----------------|----------------------------------------------------------------------------------------|

End point description:

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

End point timeframe:

During the 8-day (Days 0-7) post-vaccination period

| End point values | Combo Group | Control Group | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9 | 7 | | |
| Units: Subjects | | | | |
| Any drowsiness | 1 | 1 | | |
| Grade 3 drowsiness | 0 | 0 | | |

| | | | | |
|--------------------------|---|---|--|--|
| Related drowsiness | 1 | 0 | | |
| Any irritability | 4 | 4 | | |
| Grade 3 irritability | 0 | 0 | | |
| Related irritability | 4 | 3 | | |
| Any loss of appetite | 2 | 1 | | |
| Grade 3 loss of appetite | 0 | 0 | | |
| Related loss of appetite | 2 | 1 | | |
| Any temperature | 4 | 1 | | |
| >39.0°C | 0 | 0 | | |
| Related temperature | 4 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related solicited general symptoms for Dose 2

| | |
|-----------------|-------------------------------------------------------------------------------------------------------|
| End point title | Number of subjects with any, grade 3 and related solicited general symptoms for Dose 2 ^[5] |
|-----------------|-------------------------------------------------------------------------------------------------------|

End point description:

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

End point timeframe:

During the 8-day (Days 0-7) post-vaccination period

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: No subjects from the Control Group had received the second dose of vaccine due to study termination.

| End point values | Combo Group | | | |
|-----------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 1 | | | |
| Units: Subjects | | | | |
| Any drowsiness | 0 | | | |
| Grade 3 drowsiness | 0 | | | |
| Related drowsiness | 0 | | | |
| Any irritability | 0 | | | |
| Grade 3 irritability | 0 | | | |
| Related irritability | 0 | | | |
| Any loss of appetite | 0 | | | |
| Grade 3 loss of appetite | 0 | | | |
| Related loss of appetite | 0 | | | |
| Any temperature | 1 | | | |
| >39.0°C | 0 | | | |
| Related temperature | 1 | | | |

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

End point timeframe:

During the 8-day (Days 0-7) post-vaccination period

| End point values | Combo Group | Control Group | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9 | 7 | | |
| Units: Subjects | | | | |
| Any drowsiness | 1 | 1 | | |
| Grade 3 drowsiness | 0 | 0 | | |
| Related drowsiness | 1 | 0 | | |
| Any irritability | 4 | 4 | | |
| Grade 3 irritability | 0 | 0 | | |
| Related irritability | 4 | 3 | | |
| Any loss of appetite | 2 | 1 | | |
| Grade 3 loss of appetite | 0 | 0 | | |
| Related loss of appetite | 2 | 1 | | |
| Any temperature >39.0°C | 4 | 1 | | |
| | 0 | 0 | | |
| Related temperature | 4 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited adverse events AE(s)

| | |
|-----------------|----------------------------------------------------------|
| End point title | Number of subjects with unsolicited adverse events AE(s) |
|-----------------|----------------------------------------------------------|

End point description:

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

End point timeframe:

During the 31-day (Days 0-30) post-vaccination period

| End point values | Combo Group | Control Group | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9 | 7 | | |
| Units: Subjects | | | | |
| Any AE(s) | 2 | 3 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious AE(s)

| | |
|-------------------------|---------------------------------------|
| End point title | Number of subjects with serious AE(s) |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| During the study period | |

| End point values | Combo Group | Control Group | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9 | 7 | | |
| Units: Subjects | | | | |
| Any SAE(s) | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms: during the 8-day (Days 0-7) post-vaccination period

AEs: during the 31-day (Days 0-30) post-vaccination period

SAEs: Throughout the entire study period

Adverse event reporting additional description:

The occurrence of reported AEs (all/related) was not available and is encoded as equal to the number of subjects affected.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 12.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | Combo Group |
|-----------------------|-------------|

Reporting group description: -

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

Reporting group description: -

| Serious adverse events | Combo Group | Control Group | |
|---------------------------------------------------|---------------|---------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 7 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |

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

| Non-serious adverse events | Combo Group | Control Group | |
|-------------------------------------------------------|----------------|----------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 4 / 9 (44.44%) | 4 / 7 (57.14%) | |
| General disorders and administration site conditions | | | |
| Pain | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 2 / 9 (22.22%) | 2 / 7 (28.57%) | |
| occurrences (all) | 2 | 2 | |
| Redness | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed | 4 / 9 (44.44%) | 4 / 7 (57.14%) | |
| occurrences (all) | 4 | 4 | |
| Swelling | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 3 / 9 (33.33%) | 1 / 7 (14.29%) | |
| occurrences (all) | 3 | 1 | |
| Drowsiness | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 1 / 7 (14.29%) | |
| occurrences (all) | 1 | 1 | |
| Irritability | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 4 / 9 (44.44%) | 4 / 7 (57.14%) | |
| occurrences (all) | 4 | 4 | |
| Loss of appetite | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 2 / 9 (22.22%) | 1 / 7 (14.29%) | |
| occurrences (all) | 2 | 1 | |
| Temperature | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 4 / 9 (44.44%) | 1 / 7 (14.29%) | |
| occurrences (all) | 4 | 1 | |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 7 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eye disorders | | | |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 7 (14.29%) | |
| occurrences (all) | 0 | 1 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Rhinitis | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | 1 / 7 (14.29%) | |
| occurrences (all) | 1 | 1 | |
| Infections and infestations | | | |

| | | | |
|-----------------------------|---------------|----------------|--|
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 7 (14.29%) | |
| occurrences (all) | 0 | 1 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 23 February 2009 | <p>Amendment 1</p> <p>This protocol amendment is being prepared to allow the analysis of data pertaining to the primary vaccination phase (up to and including Visit 3) as soon as they are available. Additionally the participation of Italy was cancelled before study start hence the protocol has been updated to reflect this. Some bullets related to collection and transcription of diary cards, were misplaced in the list of procedures table which have been corrected.</p> |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

| Date | Interruption | Restart date |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 26 May 2009 | <p>The study was terminated early due to discrepancies between the initial participating countries and the actual participating one.</p> <p>It was deemed that in a single country design there was insufficient justification of using Menjugate® and that the incidence of meningococcal type C disease in children up to 2 years was too low in Slovakia. Following this decision of the Ethics Committee, the study was prematurely terminated after enrolling and vaccinating 16 subjects.</p> | - |

Notes:

Limitations and caveats

None reported