Clinical trial results:
A phase III, open, controlled study to assess the persistence of antibodies after one dose of GlaxoSmithKline Biologicals' meningococcal serogroup ACWY conjugate vaccine (MenACWY-TT) given intramuscularly versus one dose of Mencevax™ ACWY given subcutaneously to healthy subjects aged 11 through 17 years in the primary study 109069 (MenACWY-TT-036)

Summary

EudraCT number	2012-005641-21
Trial protocol	Outside EU/EEA
Global end of trial date	17 May 2013

Results information

Result version number	v2 (current)
This version publication date	07 April 2016
First version publication date	17 July 2015
Version creation reason	• New data added to full data set • Correction of full data set Data for secondary endpoints have been added. Data for rSBA seropositivity and seroconversion primary and secondary endpoints were updated.

Trial information

Trial identification

Sponsor protocol code	112148

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00974363
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	30 June 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 May 2013
Global end of trial reached?	Yes
Global end of trial date	17 May 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

At 24, 36, 48, and 60 months after primary vaccination of adolescents with Nimenrix™ or Mencevax™ ACWY vaccine:

- To evaluate the persistence of meningococcal antibodies in terms of percentage of subjects with serum bactericidal antibodies using baby rabbit complement (rSBA) titres ≥ 1:8 for each of the 4 serogroups.

Protection of trial subjects:

Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 September 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Philippines: 388
Country: Number of subjects enrolled	India: 309
Worldwide total number of subjects	697
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)	0
Adolescents (12-17 years)	697
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:

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	697
Number of subjects completed	689

Pre-assignment subject non-completion reasons

Reason: Number of subjects	No vaccination received: 8

Period 1

Period 1 title	Month 24 (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Group

Arm description:

Subjects vaccinated with a single dose of MenACWY-TT vaccine, in the primary study 109069 (NCT00464815).

Arm type	No Intervention
Investigational medicinal product name	Nimenrix™
Investigational medicinal product code	
Other name	MenACWY-TT
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACWY-TT vaccine was administered by intramuscular injection in the deltoid region of the nondominant
arm.

Arm title	Mencevax Group

Arm description:

Subjects vaccinated with a single dose of MenACWY vaccine, in the primary study 109069 (NCT00464815).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1[1]	Nimenrix Group	Mencevax Group
Started	521	168
Completed	521	168

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: No vaccination was received for 8 subjects, hence they were excluded from the study.

Baseline characteristics

Reporting groups	
Reporting group title	Nimenrix Group
Reporting group description:	
Subjects vaccinated with a single dose of MenACWY-TT vaccine, in the primary study 109069 (NCT00464815).	
Reporting group title	Mencevax Group
Reporting group description:	
Subjects vaccinated with a single dose of MenACWY vaccine, in the primary study 109069 (NCT00464815).	

Reporting group values	Nimenrix Group	Mencevax Group	Total
Number of subjects	521	168	689
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			
arithmetic mean	16.4	16.4	
standard deviation	± 1.94	± 2	-
Gender categorical			
Units: Subjects			
Female	273	86	359
Male	248	82	330

End points

End points reporting groups

Reporting group title	Nimenrix Group
Reporting group description:	
Subjects vaccinated with a single dose of MenACWY-TT vaccine, in the primary study 109069 (NCT00464815).	
Reporting group title	Mencevax Group
Reporting group description:	
Subjects vaccinated with a single dose of MenACWY vaccine, in the primary study 109069 (NCT00464815).	

Primary: Number of subjects with Meningitis A antibody titres by serum bactericidal assay (using rabbit complement) (rSBA-MenA) ≥1:8

End point title	Number of subjects with Meningitis A antibody titres by serum bactericidal assay (using rabbit complement) (rSBA-MenA) ≥1:8[1]
End point description:	
These analyses were performed by the Public Health England (PHE) laboratory and by GSK Biologicals' laboratory	
End point type	Primary
End point timeframe:	
At months 24, 36, 48 and 60 post primary 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 scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	449	150		
Units: Subjects				
rSBA-MenA M24 GSK laboratory [N=405;132]	404	132		
rSBA-MenA M36 PHE laboratory [N=449;150]	417	124		
rSBA-MenA M48 PHE laboratory [N=391;130]	353	105		
rSBA-MenA M60 PHE laboratory [N=236;86]	230	80		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenC antibody titres ≥1:8

End point title	Number of subjects with rSBA-MenC antibody titres ≥1:8[2]

End point description:

These analyses were performed by the Public Health England (PHE) laboratory and by GSK Biologicals' laboratory

End point type	Primary

End point timeframe:

At months 24, 36, 48 and 60 post primary dose

Notes:

[2] - 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	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	449	150		
Units: Subjects				
rSBA-MenC M24 GSK laboratory [N=407;132]	404	131		
rSBA-MenC M36 PHE laboratory [N=449;150]	409	129		
rSBA-MenC M48 PHE laboratory [N=390;130]	367	113		
rSBA-MenC M60 PHE laboratory [N=236;85]	209	74		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenW-135 antibody titres ≥1:8

End point title	Number of subjects with rSBA-MenW-135 antibody titres

End point description:

These analyses were performed by the Public Health England (PHE) laboratory and by GSK Biologicals' laboratory

End point type	Primary

End point timeframe:

At months 24, 36, 48 and 60 post primary dose

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	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	449	150		
Units: Subjects				
rSBA-MenW-135 M24 GSK laboratory [N=407;131]	405	124		
rSBA-MenW-135 M36 PHE laboratory [N=449;150]	368	45		
rSBA-MenW-135 M48 PHE laboratory [N=390;130]	301	35		

rSBA-MenW-135 M60 PHE laboratory [N=236;86]	203	30		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenY antibody titres ≥1:8

End point title	Number of subjects with rSBA-MenY antibody titres ≥1:8[4]

End point description:

These analyses were performed by the Public Health England (PHE) laboratory and by GSK Biologicals' laboratory

End point type	Primary

End point timeframe:

At months 24, 36, 48 and 60 post primary dose

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	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	449	150		
Units: Subjects				
rSBA-MenY M24 GSK laboratory [N=407;130]	407	126		
rSBA-MenY M36 PHE laboratory [N=449;150]	418	87		
rSBA-MenY M48 PHE laboratory [N=389;130]	348	63		
rSBA-MenY M60 PHE laboratory [N=236;86]	228	57		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA antibody titres ≥1:128

End point title	Number of subjects with rSBA-MenA antibody titres ≥1:128

End point description:

These analyses were performed by the Public Health England (PHE) laboratory and by GSK Biologicals' laboratory

End point type	Secondary

End point timeframe:

At months 24, 36, 48 and 60 post primary dose

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	449	150		
Units: Subjects				
rSBA-MenA M24 GSK laboratory [N=405;132]	403	128		
rSBA-MenA M36 PHE laboratory [N=449;150]	398	118		
rSBA-MenA M48 PHE laboratory [N=391;130]	335	99		
rSBA-MenA M60 PHE laboratory [N=236;86]	219	71		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenC antibody titres ≥1:128

End point title	Number of subjects with rSBA-MenC antibody titres ≥1:128

End point description:

These analyses were performed by the Public Health England (PHE) laboratory and by GSK Biologicals' laboratory

End point type	Secondary

End point timeframe:

At months 24, 36, 48 and 60 post primary dose

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	449	150		
Units: Subjects				
rSBA-MenC M24 GSK laboratory [N=407;132]	396	125		
rSBA-MenC M36 PHE laboratory [N=449;150]	380	117		
rSBA-MenC M48 PHE laboratory [N=390;130]	347	104		
rSBA-MenC M60 PHE laboratory [N=236;85]	188	68		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenW-135 antibody titres ≥1:128

End point title	Number of subjects with rSBA-MenW-135 antibody titres ≥1:128

End point description:

These analyses were performed by the Public Health England (PHE) laboratory and by GSK Biologicals' laboratory

End point type	Secondary

End point timeframe:

At months 24, 36, 48 and 60 post primary dose

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	449	150		
Units: Subjects				
rSBA-MenW-135 M24 GSK laboratory [N=407;131]	403	113		
rSBA-MenW-135 M36 PHE laboratory [N=449;150]	350	36		
rSBA-MenW-135 M48 PHE laboratory [N=390;130]	284	25		
rSBA-MenW-135 M60 PHE laboratory [N=236;86]	195	26		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenY antibody titres ≥1:128

End point title	Number of subjects with rSBA-MenY antibody titres ≥1:128

End point description:

These analyses were performed by the Public Health England (PHE) laboratory and by GSK Biologicals' laboratory

End point type	Secondary

End point timeframe:

At months 24, 36, 48 and 60 post primary dose

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	449	150		
Units: Subjects				
rSBA-MenY M24 GSK laboratory [N=407;130]	407	123		

rSBA-MenY M36 PHE laboratory [N=449;150]	401	77		
rSBA-MenY M48 PHE laboratory [N=389;130]	333	60		
rSBA-MenY M60 PHE laboratory [N=236;86]	225	56		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenA

End point title	Antibody titers for rSBA-MenA

End point description:

These analyses were performed by the Public Health England (PHE) laboratory and by GSK Biologicals' laboratory

End point type	Secondary

End point timeframe:

At months 24, 36, 48 and 60 post primary dose

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	449	150		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA M24 GSK laboratory [N=405;132]	1493.4 (1369 to 1629)	780.3 (665.3 to 915.2)		
rSBA-MenA M36 PHE laboratory [N=449;150]	448.3 (381.4 to 527.1)	206 (147.4 to 288.1)		
rSBA-MenA M48 PHE laboratory [N=391;130]	386.9 (321.2 to 466.2)	174.4 (121.2 to 250.8)		
rSBA-MenA M60 PHE laboratory [N=236;86]	643.8 (530.7 to 781)	296 (202.4 to 432.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenC

End point title	Antibody titers for rSBA-MenC

End point description:

These analyses were performed by the Public Health England (PHE) laboratory and by GSK Biologicals' laboratory

End point type	Secondary

End point timeframe:

At months 24, 36, 48 and 60 post primary dose

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	449	150		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenC M24 GSK laboratory [N=407;132]	1137.5 (1006.1 to 1286)	1543 (1145.8 to 2077.7)		
rSBA-MenC M36 PHE laboratory [N=449;150]	371.4 (309.4 to 445.8)	389.8 (262 to 579.9)		
rSBA-MenC M48 PHE laboratory [N=390;130]	378.5 (319.7 to 448.1)	364 (242.7 to 545.9)		
rSBA-MenC M60 PHE laboratory [N=236;85]	248.6 (194.2 to 318.2)	366.5 (224.1 to 599.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenW-135

End point title	Antibody titers for rSBA-MenW-135

End point description:

These analyses were performed by the Public Health England (PHE) laboratory and by GSK Biologicals' laboratory

End point type	Secondary

End point timeframe:

At months 24, 36, 48 and 60 post primary dose

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	449	150		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenW-135 M24 GSK laboratory [N=407;131]	1977.6 (1775 to 2203.4)	418.2 (317.6 to 550.6)		
rSBA-MenW-135 M36 PHE laboratory [N=449;150]	338 (268.4 to 425.6)	16 (10.9 to 23.6)		
rSBA-MenW-135 M48 PHE laboratory [N=390;130]	209.8 (163.9 to 268.6)	11.7 (8.2 to 16.8)		
rSBA-MenW-135 M60 PHE laboratory [N=236;86]	436.9 (324.4 to 588.4)	19.7 (11.8 to 32.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenY

End point title	Antibody titers for rSBA-MenY

End point description:

These analyses were performed by the Public Health England (PHE) laboratory and by GSK Biologicals' laboratory

End point type	Secondary

End point timeframe:

At months 24, 36, 48 and 60 post primary dose

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	449	150		
Units: Titer				
geometric mean (confidence interval 95%)				
rSBA-MenY M24 GSK laboratory [N=407;130]	3502.5 (3203.2 to 3829.7)	1028.3 (797.3 to 1326.1)		
rSBA-MenY M36 PHE laboratory [N=449;150]	740.5 (620 to 884.3)	69.6 (44.6 to 108.6)		
rSBA-MenY M48 PHE laboratory [N=389;130]	533.4 (430 to 661.7)	49.8 (30.7 to 80.9)		
rSBA-MenY M60 PHE laboratory [N=236;86]	1000.2 (824.1 to 1214)	124.9 (71.2 to 219.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-polysaccharide A (anti-PSA), anti-polysaccharide C (anti-PSC), anti-polysaccharide W-135 (anti-PSW-135) and anti-polysaccharide Y (anti-PSY) antibody concentrations equal to or above the cut-off values

End point title	Number of subjects with anti-polysaccharide A (anti-PSA), anti-polysaccharide C (anti-PSC), anti-polysaccharide W-135 (anti-PSW-135) and anti-polysaccharide Y (anti-PSY) antibody concentrations equal to or above the cut-off values

End point description:

These analyses were performed by the GSK Biologicals' laboratory

End point type	Secondary
End point timeframe:	
At month 24	

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	208	66		
Units: Subjects				
Anti-PSA ≥ 0.3 µg/mL [N=196; 65]	196	65		
Anti-PSA ≥ 2.0 µg/mL [N=196; 65]	179	64		
Anti-PSC ≥ 0.3 µg/mL [N=192; 66]	176	66		
Anti-PSC ≥ 2.0 µg/mL [N=192; 66]	96	62		
Anti-PSW-135 ≥ 0.3 µg/mL [N=198; 62]	187	61		
Anti-PSW-135 ≥ 2.0 µg/mL [N=198; 62]	127	49		
Anti-PSY ≥ 0.3 µg/mL [N=208; 65]	203	63		
Anti-PSY ≥ 2.0 µg/mL [N=208; 65]	130	51		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibodies

End point title	Concentrations of anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibodies
End point description:	

End point type	Secondary
End point timeframe:	
At month 24	

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	208	66		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA [N=196; 65]	10.16 (8.47 to 12.2)	18.17 (13.33 to 24.77)		
Anti-PSC [N=192; 66]	1.95 (1.61 to 2.35)	10.88 (8.22 to 14.41)		
Anti-PSW-135 [N=198; 62]	3.29 (2.71 to 4)	5.22 (3.74 to 7.27)		

Anti-PSY [N=208; 65]	3.63 (3 to 4.4)	6.99 (4.83 to 10.11)		

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:

End point type	Secondary

End point timeframe:

At months 24, 36, 48 and 60

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	521	168		
Units: Subjects				
SAEs Month 24 [N=521;168]	0	0		
SAEs Month 36 [N=488;155]	0	0		
SAEs Month 48 [N=407;134]	0	0		
SAEs Month 60 [N=356;122]	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Serious adverse events (SAEs): up to Month 24, 36, 48 and 60.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups

Reporting group title	Mencevax Group

Reporting group description:

Subjects vaccinated with a single dose of MenACWY vaccine.

Reporting group title	Nimenrix Group

Reporting group description:

Subjects vaccinated with a single dose of MenACWY-TT vaccine.

Serious adverse events	Mencevax Group	Nimenrix Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 168 (0.00%)	0 / 521 (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	Mencevax Group	Nimenrix Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 168 (0.00%)	0 / 521 (0.00%)	

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: No information about unsolicited AEs was collected during this study as no product was administered.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 December 2011	The primary objective of the study was to evaluate the persistence of meningococcal antibodies in terms of the percentage of subjects with rabbit serum bactericidal assay (rSBA) titres ≥1:8 for each of the four serogroups (rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY) at 24, 36, 48 and 60 months after primary vaccination of adolescents with MenACWY-TT or Mencevax™ ACWY vaccine. To support the data obtained by rSBA testing, antibody concentrations against meningococcal polysaccharides are planned to be assessed by ELISA (anti-polysaccharides [PS] testing) at 24, 36, 48 and 60 months after primary vaccination with MenACWY-TT. The anti-PS testing will be performed at 24 months after vaccine administration, but the sponsor decided not to perform the anti-PS testing at 36, 48 and 60 months after vaccine administration for the following reasons: •the World Health Organisation (WHO) considers SBA the primary means of assessing immune response to meningococcal conjugate vaccines [WHO, 2006; WHO, 1999]. •circulating bactericidal antibodies are more critical for persistent protection against meningococcal disease than non-functional antibodies against meningococcal polysaccharides [Centres for Disease Control (CDC), 2011; WHO, 2006]. Although antibody concentrations will not be determined by ELISA at 36, 48 and 60 months after primary vaccination with MenACWY-TT or, all subjects will be informed of their rSBA antibody titres at each immunogenicity time point when statistical analyses at that time point have been completed. In addition: •The protocol amendment clarifies in which laboratory the different assays will be performed. •The introduction has been updated with the current licensing status of competitor vaccines and the current recommendations for meningococcal vaccines. The rationale for the study has been updated according to this new information. •The list of abbreviations and reference list have been updated according to changes in the clinical study team.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported