Clinical trial results:
A Phase 2, Open-label, Controlled, Multi-Center Extension Study to Evaluate 4-Year Antibody Persistence and Booster Response Following MenABCWY Vaccination in Healthy Adolescents and Young Adults who Previously Participated in Studies V102_02 (NCT01210885) and V102_02E1 (NCT01367158).

Summary

EudraCT number	2016-004420-29
Trial protocol	Outside EU/EEA
Global end of trial date	10 December 2015

Results information

Result version number	v1
This version publication date	16 March 2017
First version publication date	16 March 2017

Trial information

Trial identification

Sponsor protocol code	205213

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02451514
WHO universal trial number (UTN)	-

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	07 November 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 November 2015
Global end of trial reached?	Yes
Global end of trial date	10 December 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

• To assess the antibody persistence against N. meningitidis serogroups A, C, W and Y and serogroup B test strains in subjects who previously received MenABCWY+OMV or MenACWY approximately 4 years earlier, as measured by the percentage of subjects with hSBA titers ≥ lower limit quantitation (LLQ) and other thresholds, hSBA Geometric Mean Titers (GMTs) and geometric mean ratios (GMRs).
• To evaluate the immune response against N. meningitidis serogroups A, C, W and Y and serogroup B test strains 30 days after a single dose of MenABCWY+OMV in previously vaccinated subjects, and in vaccine-naïve subjects (VNS) of similar age, as measured by the percentage of subjects with hSBA titers ≥LLQ and other thresholds, hSBA GMTs and GMRs.

Protection of trial subjects:

The study was conducted in compliance with the protocol, Good Clinical Practices (GCPs) and applicable regulatory requirement(s). This clinical study was designed, implemented and reported in accordance with the ICH Harmonized Tripartite Guidelines for Good Clinical Practice, with applicable local regulations, Novartis codes on protection of human rights, and with the ethical principles laid down in the Declaration of Helsinki (European Council 2001, US Code of Federal Regulations, ICH 1997).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 June 2015
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	Chile: 13
Country: Number of subjects enrolled	Panama: 88
Country: Number of subjects enrolled	Colombia: 28
Worldwide total number of subjects	129
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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	45
Adults (18-64 years)	84
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from 5 sites in Panama, 3 sites in Colombia and 1 site in Chile.

Pre-assignment

Screening details:

Healthy adolescents and young adults, who previously participated in studies V102_02 (NCT01210885) and V102_02E1 (NCT01367158) and who received a 2-dose series of MenABCWY+OMV or 1 dose of Menveo (MenACWY), were included in the present study, along with vaccine-naïve subjects of similar age.

Period 1

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

Blinding implementation details:

The study was an open-label study. Therefore, no blinding procedures were utilized.

Arms

Are arms mutually exclusive?	Yes
Arm title	MenABCWY+OMV Group

Arm description:

Subjects who received 2 doses of MenABCWY+OMV vaccine in the parent study V102_02 (NCT01210885) and received no subsequent meningococcal vaccines, received a booster dose of MenABCWY+OMV vaccine in the current study at Day 1.

Arm type	Experimental
Investigational medicinal product name	Meningococcal (groups A, C, W, Y-135) Oligosaccharide Diphtheria CRM197 Conjugate combined with Meningococcal (group B) Multi-Component Recombinant Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose (0.5 mL)

Arm title	MenACWY Group

Arm description:

Subjects who received MenACWY vaccine in the parent study V102_02 (NCT01210885) and received no subsequent meningococcal vaccines, received 2 doses of MenABCWY+OMV vaccine, one month apart (Day 1 and Day 31), in the current study.

Arm type	Experimental
Investigational medicinal product name	Meningococcal (groups A, C, W, Y-135) Oligosaccharide Diphtheria CRM197 Conjugate combined with Meningococcal (group B) Multi-Component Recombinant Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses (0.5 mL each), 1 month apart

Arm title	Naive Group

Arm description:

Subjects similar in age to subjects in the MenABCWY+OMV and MenACWY groups, who had not previously received any meningococcal vaccine and who received 2 doses of MenABCWY+OMV vaccine, 1 month apart (Day 1 and Day 31), in the current study.

Arm type	Experimental
Investigational medicinal product name	Meningococcal (groups A, C, W, Y-135) Oligosaccharide Diphtheria CRM197 Conjugate combined with Meningococcal (group B) Multi-Component Recombinant Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses (0.5 mL each), 1 month apart

Number of subjects in period 1	MenABCWY+OMV Group	MenACWY Group	Naive Group
Started	33	46	50
Completed	33	46	50

Baseline characteristics

Reporting groups	
Reporting group title	MenABCWY+OMV Group
Reporting group description:	
Subjects who received 2 doses of MenABCWY+OMV vaccine in the parent study V102_02 (NCT01210885) and received no subsequent meningococcal vaccines, received a booster dose of MenABCWY+OMV vaccine in the current study at Day 1.	
Reporting group title	MenACWY Group
Reporting group description:	
Subjects who received MenACWY vaccine in the parent study V102_02 (NCT01210885) and received no subsequent meningococcal vaccines, received 2 doses of MenABCWY+OMV vaccine, one month apart (Day 1 and Day 31), in the current study.	
Reporting group title	Naive Group
Reporting group description:	
Subjects similar in age to subjects in the MenABCWY+OMV and MenACWY groups, who had not previously received any meningococcal vaccine and who received 2 doses of MenABCWY+OMV vaccine, 1 month apart (Day 1 and Day 31), in the current study.	

Reporting group values	MenABCWY+OMV Group	MenACWY Group	Naive Group
Number of subjects	33	46	50
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	12	14	19
Adults (18-64 years)	21	32	31
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	18.61	18.72	17.96
standard deviation	± 2.207	± 1.87	± 2.04
Gender categorical Units: Subjects			
Female	22	27	25
Male	11	19	25

Reporting group values	Total		
Number of subjects	129		
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)	45		
Adults (18-64 years)	84		
From 65-84 years	0		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	74		
Male	55		

End points

End points reporting groups

Reporting group title	MenABCWY+OMV Group
Reporting group description:	
Subjects who received 2 doses of MenABCWY+OMV vaccine in the parent study V102_02 (NCT01210885) and received no subsequent meningococcal vaccines, received a booster dose of MenABCWY+OMV vaccine in the current study at Day 1.	
Reporting group title	MenACWY Group
Reporting group description:	
Subjects who received MenACWY vaccine in the parent study V102_02 (NCT01210885) and received no subsequent meningococcal vaccines, received 2 doses of MenABCWY+OMV vaccine, one month apart (Day 1 and Day 31), in the current study.	
Reporting group title	Naive Group
Reporting group description:	
Subjects similar in age to subjects in the MenABCWY+OMV and MenACWY groups, who had not previously received any meningococcal vaccine and who received 2 doses of MenABCWY+OMV vaccine, 1 month apart (Day 1 and Day 31), in the current study.	

Primary: Percentage of subjects with hSBA ≥ LLQ against N. meningitidis serogroups A, C, W and Y and serogroup B test strains

End point title	Percentage of subjects with hSBA ≥ LLQ against N. meningitidis serogroups A, C, W and Y and serogroup B test strains[1]

End point description:

Antibody levels against N. meningitidis serogroups A, C, W and Y and serogroup B test strains (H44/76, 5/99, M14459, M07-024184, M01-0240364, NZ98/254) in subjects who previously received MenABCWY+OMV or MenACWY approximately 4 years earlier, and in Naïve subjects, as measured by the percentages of subjects with hSBA (human serum bactericidal assay) ≥ LLQ (lower limit of quantitation). The data were reported based on the FAS (Full Analysis Set) immunogenicity persistence population set, which included all subjects in the Enrolled population who provided at least one evaluable serum sample at baseline (Visit 1 in V102_02E2) and whose assay results were available for at least one strain.

End point type	Primary

End point timeframe:

Day 1 (4 years persistence)

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 immunogenicity results will be updated when they become available.

End point values	MenABCWY+OMV Group	MenACWY Group	Naive Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[2]	0[3]	0[4]	
Units: Percentage				
number (confidence interval 95%)				
Serogroup A	(to)	(to)	(to)	
Serogroup C	(to)	(to)	(to)	
Serogroup W	(to)	(to)	(to)	
Serogroup Y	(to)	(to)	(to)	
H44/76	(to)	(to)	(to)	
5/99	(to)	(to)	(to)	

M14459	(to)	(to)	(to)	
M07-024184	(to)	(to)	(to)	
M01-0240364	(to)	(to)	(to)	
NZ98/254	(to)	(to)	(to)	

Notes:

[2] - The immunogenicity results will be updated when they become available.

[3] - The immunogenicity results will be updated when they become available.

[4] - The immunogenicity results will be updated when they become available.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any unsolicited and solicited adverse events (AEs) within 30 min after each vaccination

End point title	Number of subjects reporting any unsolicited and solicited adverse events (AEs) within 30 min after each vaccination

End point description:

Any solicited and unsolicited AEs reported within 30 minutes after each vaccination. Assessed solicited local symptoms were: Erythema, Swelling and Induration. Any = occurrence of the symptom spreading beyond 25 millimeters (mm) of injection site. Assessed solicited general symptoms were: Arthralgia, Chills, Fatigue, Headache, Loss of Appetite, Myalgia, Nausea and Fever (body temperature ≥ 38°C). Other solicited data included: Prevention of Pain and/or Fever and Treatment of Pain and/or Fever. Any = occurrence of the symptom regardless of intensity grade.
Note: There were no unsolicited AEs reported within 30 minutes after vaccination.
The data were reported based on the Solicited Safety Set, which included all subjects in the FAS Immunogenicity population who provided post-vaccination reactogenicity data.

End point type	Secondary

End point timeframe:

Within 30 min after each vaccination

End point values	MenABCWY+OMV Group	MenACWY Group	Naive Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	33	46	50	
Units: Subjects				
Erythema (1st vacc.) (N=33;46;50)	0	1	0	
Erythema (2nd vacc.) (N=0;44;50)	0	1	0	
Induration (1st vacc.) (N=33;46;50)	0	0	0	
Induration (2nd vacc.) (N=0;44;50)	0	0	0	
Pain (1st vacc.) (N=33;46;50)	4	8	6	
Pain (2nd vacc.) (N=0;44;50)	0	3	4	
Arthralgia (1st vacc.) (N=33;46;50)	0	0	0	
Arthralgia (2nd vacc.) (N=0;44;50)	0	0	0	
Chills (1st vacc.) (N=33;46;50)	0	0	0	
Chills (2nd vacc.) (N=0;44;50)	0	0	0	
Fatigue (1st vacc.) (N=33;46;50)	0	0	0	
Fatigue (2nd vacc.) (N=0;44;50)	0	0	1	
Headache (1st vacc.) (N=33;46;50)	1	0	0	
Headache (2nd vacc.) (N=0;44;50)	0	0	1	
Loss of Appetite (1st vacc.) (N=33;46;50)	0	0	0	

Loss of Appetite (2nd vacc.) (N=0;44;50)	0	0	0	
Myalgia (1st vacc.) (N=33;46;50)	0	0	0	
Myalgia (2nd vacc.) (N=0;44;50)	0	0	0	
Nausea (1st vacc.) (N=33;46;50)	0	0	0	
Nausea (2nd vacc.) (N=0;44;50)	0	0	0	
Fever (1st vacc.) (N=33;46;50)	0	0	0	
Fever (2nd vacc.) (N=0;44;50)	0	0	0	
Prevention of Pain/Fever (1st vacc.) (N=33;45;50)	0	0	0	
Prevention of Pain/Fever (2nd vacc.) (N=0;44;50)	0	0	1	
Treatment of Pain/Fever (1st vacc.) (N=33;45;50)	0	0	0	
Treatment of Pain/Fever (2nd vacc.) (N=0;44;50)	0	0	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any solicited local symptoms

End point title	Number of subjects with any solicited local symptoms

End point description:

Assessed solicited local symptoms were Erythema, Induration and Pain. Any = occurrence of the symptom spreading beyond 25 millimeters (mm) of injection site.
The data were reported based on the Solicited Safety Set, which included all subjects in the FAS Immunogenicity population who provided post-vaccination reactogenicity data.

End point type	Secondary

End point timeframe:

From Day 1 (6 h) to Day 7 after each vaccination

End point values	MenABCWY+OMV Group	MenACWY Group	Naive Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	33	46	50	
Units: Subjects				
Any local AEs (1st vacc.) (N=33;46;50)	31	41	47	
Erythema (1st vacc.) (N=33;45;50)	8	7	8	
Induration (1st vacc.) (N=33;46;50)	12	7	13	
Pain (1st vacc.) (N=33;46;50)	31	41	47	
Any local AEs (2nd vacc.) (N=0;45;50)	0	35	41	
Erythema (2nd vacc.) (N=0;45;49)	0	6	7	
Induration (2nd vacc.) (N=0;45;50)	0	9	8	
Pain (2nd vacc.) (N=0;45;50)	0	34	41	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited systemic symptoms and other solicited data

End point title	Number of subjects with solicited systemic symptoms and other solicited data

End point description:

Assessed solicited systemic symptoms were Arthralgia, Chills, Fatigue, Headache, Loss of Appetite, Myalgia, Nausea and Fever (body temperature ≥ 38°C). Other solicited data included: Prevention of pain and/or fever and Treatment of pain and/or fever. Any = occurrence of the symptom regardless of intensity grade.
The data were reported based on the Solicited Safety Set, which included all subjects in the FAS Immunogenicity population who provided post-vaccination reactogenicity data.

End point type	Secondary

End point timeframe:

From Day 1 (6 h) to Day 7 after each vaccination

End point values	MenABCWY+OMV Group	MenACWY Group	Naive Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	33	46	50	
Units: Subjects				
Any systemic AEs (1st vacc.) (N=33;46;50)	24	35	37	
Arthralgia (1st vacc.) (N=33;46;50)	8	8	15	
Chills (1st vacc.) (N=33;46;50)	5	11	11	
Fatigue (1st vacc.) (N=33;45;50)	14	19	24	
Headache (1st vacc.) (N=33;46;50)	19	20	23	
Loss of Appetite (1st vacc.) (N=33;45;50)	5	9	9	
Myalgia (1st vacc.) (N=33;46;50)	18	22	23	
Nausea (1st vacc.) (N=33;46;50)	4	10	13	
Fever (1st vacc.) (N=33;46;50)	0	4	8	
Prevention of Pain/Fever (1st vacc.) (N=33;44;50)	0	1	1	
Treatment of Pain/Fever (1st vacc.) (N=33;44;50)	8	7	11	
Any systemic AEs (2nd vacc.) (N=0;45;50)	0	22	28	
Arthralgia (2nd vacc.) (N=0;45;50)	0	4	7	
Chills (2nd vacc.) (N=0;45;50)	0	5	9	
Fatigue (2nd vacc.) (N=0;44;50)	0	10	12	
Headache (2nd vacc.) (N=0;44;50)	0	11	18	
Loss of Appetite (2nd vacc.) (N=0;45;50)	0	3	5	
Myalgia (2nd vacc.) (N=0;45;50)	0	12	14	
Nausea (2nd vacc.) (N=0;45;50)	0	4	4	
Fever (2nd vacc.) (N=0;45;50)	0	4	2	
Prevention of Pain/Fever (2nd vacc.) (N=0;45;50)	0	1	3	
Treatment of Pain/Fever (2nd vacc.) (N=0;45;50)	0	2	6	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited AEs

End point title	Number of subjects with unsolicited 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. Possibly or Probably related = AE assessed by the investigator as related to the vaccination.
The data were reported based on the Unsolicited Safety Set, which included all subjects in the Exposed Set who had post-vaccination unsolicited adverse event records.

End point type	Secondary

End point timeframe:

From Day 1 to Day 31

End point values	MenABCWY+OMV Group	MenACWY Group	Naive Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	33	46	50	
Units: Subjects				
Any AEs	11	21	20	
Possibly or Probably Related AEs	3	11	8	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with medically attended AEs reported during the entire study period

End point title	Number of subjects with medically attended AEs reported during the entire study period

End point description:

Medically attended AEs = were defined as events for which the subject received medical attention defined as hospitalization, an emergency room visit, or a visit to or from medical personnel (medical doctor) for any reason. Any medically attended AE(s) = Occurrence of any medically attended AE(s) regardless of intensity grade or relation to vaccination.
The data were reported based on the Unsolicited Safety Set, which included all subjects in the Exposed Set who had post-vaccination unsolicited adverse event records.

End point type	Secondary

End point timeframe:

From Day 1 to Day 31 (MenABCWY+OMV Group) and from Day 1 to Day 61 (MenACWY and Naive Groups)

End point values	MenABCWY+OMV Group	MenACWY Group	Naive Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	33	46	50	
Units: Subjects				
Medically attended AEs	2	6	5	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited AEs leading to premature withdrawal from study reported during the entire study period

End point title	Number of subjects with unsolicited AEs leading to premature withdrawal from study reported during the entire study period

End point description:

The number of subjects who reported unsolicited AEs leading to premature withdrawal from study after any vaccination.
The data were reported based on the Unsolicited Safety Set, which included all subjects in the Exposed Set who had post-vaccination unsolicited adverse event records.

End point type	Secondary

End point timeframe:

From Day 1 to Day 31 (MenABCWY+OMV Group) and from Day 1 to Day 61 (MenACWY and Naive Groups)

End point values	MenABCWY+OMV Group	MenACWY Group	Naive Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	33	46	50	
Units: Subjects				
AEs leading to premature withdrawal	0	1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events (SAEs) reported during the entire study period

End point title	Number of subjects with serious adverse events (SAEs) reported during the entire study period

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. Any SAE(s) = Occurrence of any SAE(s) regardless of intensity grade or relation to vaccination. Possibly or probably related SAE(s) = SAE(s) assessed by the investigator as related to the vaccination.
The data were reported based on the Unsolicited Safety Set, which included all subjects in the Exposed Set who had post-vaccination unsolicited adverse event records.

End point type	Secondary

End point timeframe:

From Day 1 to Day 31 (MenABCWY+OMV Group) and from Day 1 to Day 61 (MenACWY and Naive Groups)

End point values	MenABCWY+OMV Group	MenACWY Group	Naive Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	33	46	50	
Units: Subjects				
Any SAEs	0	0	0	
Possibly or probably related SAEs	0	0	0	
AEs leading to death	0	0	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited local and systemic symptoms: from Day 1 (6 hours) to Day 7 after each study vaccination; Unsolicited AEs: from Day 1 to Day 31 after each study vaccination; SAEs: during the entire study period (from Day 1 to Day 61).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	MenABCWY+OMV Group

Reporting group description:

Subjects who received 2 doses of MenABCWY+OMV vaccine in the parent study V102_02 (NCT01210885) and received no subsequent meningococcal vaccines, received a booster dose of MenABCWY+OMV vaccine in the current study at Day 1.

Reporting group title	MenACWY Group

Reporting group description:

Subjects who received MenACWY vaccine in the parent study V102_02 (NCT01210885) and received no subsequent meningococcal vaccines, received 2 doses of MenABCWY+OMV vaccine, one month apart (Day 1 and Day 31), in the current study.

Reporting group title	Naive Group

Reporting group description:

Subjects similar in age to subjects in the MenABCWY+OMV and MenACWY groups, who had not previously received any meningococcal vaccine and who received 2 doses of MenABCWY+OMV vaccine, 1 month apart (Day 1 and Day 31), in the current study.

Serious adverse events	MenABCWY+OMV Group	MenACWY Group	Naive Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 33 (0.00%)	0 / 46 (0.00%)	0 / 50 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

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

Non-serious adverse events	MenABCWY+OMV Group	MenACWY Group	Naive Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 33 (100.00%)	44 / 46 (95.65%)	48 / 50 (96.00%)
Nervous system disorders			
Headache			

subjects affected / exposed	19 / 33 (57.58%)	23 / 46 (50.00%)	28 / 50 (56.00%)
occurrences (all)	43	84	120
General disorders and administration site conditions			
Chills			
subjects affected / exposed	5 / 33 (15.15%)	14 / 46 (30.43%)	16 / 50 (32.00%)
occurrences (all)	10	25	31
Fatigue			
subjects affected / exposed	14 / 33 (42.42%)	20 / 46 (43.48%)	27 / 50 (54.00%)
occurrences (all)	29	75	82
Injection site erythema			
subjects affected / exposed	11 / 33 (33.33%)	26 / 46 (56.52%)	30 / 50 (60.00%)
occurrences (all)	45	135	123
Injection site induration			
subjects affected / exposed	18 / 33 (54.55%)	27 / 46 (58.70%)	30 / 50 (60.00%)
occurrences (all)	75	173	169
Injection site pain			
subjects affected / exposed	31 / 33 (93.94%)	42 / 46 (91.30%)	48 / 50 (96.00%)
occurrences (all)	114	295	333
Pyrexia			
subjects affected / exposed	0 / 33 (0.00%)	8 / 46 (17.39%)	10 / 50 (20.00%)
occurrences (all)	0	12	13
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	4 / 33 (12.12%)	10 / 46 (21.74%)	15 / 50 (30.00%)
occurrences (all)	11	30	25
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	8 / 33 (24.24%)	11 / 46 (23.91%)	19 / 50 (38.00%)
occurrences (all)	14	35	51
Myalgia			
subjects affected / exposed	18 / 33 (54.55%)	25 / 46 (54.35%)	26 / 50 (52.00%)
occurrences (all)	42	85	96
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 33 (3.03%)	6 / 46 (13.04%)	1 / 50 (2.00%)
occurrences (all)	1	6	1

Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	5 / 33 (15.15%) 11	11 / 46 (23.91%) 25	13 / 50 (26.00%) 30

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 November 2014	Allow pregnancy test be performed in urine or blood sample.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported