



Clinical trial results:

Phase 3b, Open label, Uncontrolled, Single-arm, Single-centre Study to Evaluate the Safety of Two Doses of Novartis Meningococcal Group B Vaccine When Administered to Healthy Adults from 18 to 50 Years of Age and to Collect Blood Donations to Develop Vaccines against *Neisseria meningitidis*

Summary

EudraCT number	2014-002972-95
Trial protocol	PL
Global end of trial date	24 April 2015

Results information

Result version number	v1 (current)
This version publication date	18 February 2016
First version publication date	18 February 2016

Trial information

Trial identification

Sponsor protocol code	V72_74
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02305446
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma Services A.G.
Sponsor organisation address	Fabrikstrasse 2, Basel, Switzerland, 4056
Public contact	Posting Director, Novartis Vaccines and Diagnostics, RegistryContactVaccinesUS@novartis.com
Scientific contact	Posting Director, Novartis Vaccines and Diagnostics, RegistryContactVaccinesUS@novartis.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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 August 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 April 2015
Global end of trial reached?	Yes
Global end of trial date	24 April 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To establish a control sera panel using pre and post-vaccination blood donations to be used as a reference in SBA test.

To assess the safety of two doses of rMenB+OMV NZ in healthy adult subjects.

Protection of trial subjects:

This clinical study was designed, implemented and reported in accordance with the International Conference on Harmonization (ICH) Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), with applicable local regulations, including the European Directive 2001/20/EC, Novartis codes on the protection of human rights, and with the ethical principles laid down in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 December 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	Poland: 55
Worldwide total number of subjects	55
EEA total number of subjects	55

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)	0
Adults (18-64 years)	55
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were enrolled at one site in Poland from December 2014 to February 2015.

Pre-assignment

Screening details:

All enrolled subjects were included in the trial and assigned to the same treatment group.

Period 1

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

Arms

Arm title	rMenB+OMV NZ
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Arm description:

Subjects who received two doses of rMenB+OMV NZ according to a 0, 2-month schedule.

Arm type	Experimental
Investigational medicinal product name	Meningococcal (group B) multicomponent recombinant adsorbed vaccine
Investigational medicinal product code	
Other name	rMenB+OMV NZ
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One dose (0.5 mL) vaccine administered by intramuscular (IM) injection in the deltoid area of the non-dominant arm.

Number of subjects in period 1	rMenB+OMV NZ
Started	55
Completed	54
Not completed	1
Adverse Event	1

Baseline characteristics

Reporting groups

Reporting group title	rMenB+OMV NZ
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Reporting group description:

Subjects who received two doses of rMenB+OMV NZ according to a 0, 2-month schedule.

Reporting group values	rMenB+OMV NZ	Total	
Number of subjects	55	55	
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	27.2		
standard deviation	± 6.932	-	
Gender categorical			
Units: Subjects			
Female	27	27	
Male	28	28	

End points

End points reporting groups

Reporting group title	rMenB+OMV NZ
Reporting group description: Subjects who received two doses of rMenB+OMV NZ according to a 0, 2-month schedule.	
Subject analysis set title	All Enrolled Set
Subject analysis set type	Full analysis
Subject analysis set description: All screened subjects who provide informed consent and provide demographic and/or other baseline screening measurements, regardless of the subject's vaccination status in the trial, and receive a subject ID.	
Subject analysis set title	Unsolicited Safety Set
Subject analysis set type	Safety analysis
Subject analysis set description: All subjects in the Exposed Set with post-vaccination unsolicited adverse event data.	

Primary: 1. Number of Subjects Reporting Unsolicited AEs

End point title	1. Number of Subjects Reporting Unsolicited AEs ^[1]
End point description: Safety was assessed as the number of the subjects who reported unsolicited AEs following vaccination. Analysis were evaluated on the Unsolicited Safety Set.	
End point type	Primary
End point timeframe: From day 1 to day 7 after each vaccination	

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: Statistical analyses not applicable.

End point values	rMenB+OMV NZ			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: Number of subjects				
Any SAEs (vaccination 1)	0			
Any SAEs (vaccination 2)	0			
At least possibly related SAEs (vaccination 1)	0			
At least possibly related SAEs (vaccination 2)	0			
AEs leading to premature withdrawal (vaccination1)	0			
AEs leading to premature withdrawal (vaccination2)	0			
Medically attended AEs (vaccination 1)	0			
Medically attended AEs (vaccination 2)	0			
AESIs (AEs of Special Interest) (vaccination 1)	0			
AESIs (AEs of Special Interest) (vaccination 2)	0			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: 2. Number of Adult Volunteers Whose Blood Can be Used as a Reference in SBA Test.

End point title	2. Number of Adult Volunteers Whose Blood Can be Used as a Reference in SBA Test.
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End point description:

The number of identified healthy adult volunteers with pre and post-vaccination blood donations were summarized to establish a control sera panel to be used as a reference in SBA test.
The analysis was performed on the all enrolled dataset.

End point type	Other pre-specified
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End point timeframe:

Study day 1 blood sample was drawn between day -5 and day 1.

Postvaccination 2 blood sample was drawn between day 23 and day 37 postvaccination 2.

End point values	rMenB+OMV NZ			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: Number of Subjects				
Study Day 1 Blood Sample	55			
Postvaccination 2 Blood Sample	50			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Safety was assessed from the day of first vaccination (Day 1) until and inclusive the day of study termination (pre-planned at Day 91).

Adverse event reporting additional description:

The analyses for unsolicited adverse events were done on the safety population. This study collects: throughout the study, any SAEs, AEs leading to withdrawal, AESI and medically attended AEs.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.0
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Reporting groups

Reporting group title	rMenB+OMV NZ
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Reporting group description:

Subjects who received two doses of rMenB+OMV NZ according to a 0, 2-month schedule.

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: Statistical analyses not applicable.

Serious adverse events	rMenB+OMV NZ		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 55 (1.82%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Nervous system disorders			
multiple sclerosis			
subjects affected / exposed	1 / 55 (1.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	rMenB+OMV NZ		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 55 (0.00%)		

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