



Clinical trial results:

A Phase 2, Non-Randomized, controlled, Open-Label, Parallel-Group, Extension Study to Evaluate the Immunogenicity and Safety of the Second Dose of GBS Trivalent Vaccine in Healthy Non-pregnant Subjects.

Summary

EudraCT number	2015-003094-15
Trial protocol	BE
Global end of trial date	02 November 2016

Results information

Result version number	v3 (current)
This version publication date	12 May 2019
First version publication date	15 November 2017
Version creation reason	• Correction of full data set Additional justification for missing anti-diphtheria results

Trial information

Trial identification

Sponsor protocol code	205421
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02690181
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals S.A
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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	25 May 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 November 2016
Global end of trial reached?	Yes
Global end of trial date	02 November 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the immunogenicity of a second dose of GBS Trivalent Vaccine (without adjuvant) administered approximately 4-6 years after the initial GBS vaccination, measured by ELISA.

To assess the safety and tolerability of a second dose of GBS Trivalent Vaccine (without adjuvant) administered approximately 4-6 years after the initial dose.

Protection of trial subjects:

This clinical study was designed, implemented and reported in accordance with the ICH Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), with applicable local regulations, including the European Directive 2001/20/EC, the US CFR Title 21, and Japanese Ministry of Health, Labor, and Welfare, GSK codes on the 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	29 March 2016
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	Belgium: 80
Worldwide total number of subjects	80
EEA total number of subjects	80

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)	80

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from 1 site in Belgium.

Pre-assignment

Screening details:

All enrolled subjects completed the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
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Arm title	GBS NoAdj/GBS NoAdj Group
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Arm description:

Subjects who had received unadjuvanted GBS Trivalent Vaccine in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 - NCT02690181).

Arm type	Experimental
Investigational medicinal product name	Group B Streptococcus Trivalent Glycoconjugate Vaccine
Investigational medicinal product code	
Other name	GBS Trivalent Vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL delivered by the IM route, preferably the deltoid muscle in the non-dominant arm

Arm title	GBS Alum/GBS NoAdj Group
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Arm description:

Subjects who had received GBS Trivalent Vaccine with alum adjuvant in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 - NCT02690181).

Arm type	Experimental
Investigational medicinal product name	Group B Streptococcus Trivalent Glycoconjugate Vaccine
Investigational medicinal product code	
Other name	GBS Trivalent Vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL delivered by the IM route, preferably the deltoid muscle in the non-dominant arm

Arm title	GBS MF59 Half/GBS NoAdj Group
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Arm description:

Subjects who had received GBS Trivalent Vaccine with half dose of MF59 in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 - NCT02690181).

Arm type	Experimental
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Investigational medicinal product name	Group B Streptococcus Trivalent Glycoconjugate Vaccine
Investigational medicinal product code	
Other name	GBS Trivalent Vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5 mL delivered by the IM route, preferably the deltoid muscle in the non-dominant arm	
Arm title	GBS MF59 Full/GBS NoAdj Group

Arm description:

Subjects who had received GBS Trivalent Vaccine with full dose of MF59 in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 - NCT02690181).

Arm type	Experimental
Investigational medicinal product name	Group B Streptococcus Trivalent Glycoconjugate Vaccine
Investigational medicinal product code	
Other name	GBS Trivalent Vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5 mL delivered by the IM route, preferably the deltoid muscle in the non-dominant arm	
Arm title	Placebo/GBS NoAdj Group

Arm description:

Subjects who had received placebo in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 - NCT02690181).

Arm type	Experimental
Investigational medicinal product name	Group B Streptococcus Trivalent Glycoconjugate Vaccine
Investigational medicinal product code	
Other name	GBS Trivalent Vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5 mL delivered by the IM route, preferably the deltoid muscle in the non-dominant arm	
Arm title	Naive/GBS NoAdj Group

Arm description:

Healthy non-pregnant female subjects aged 22 through 46 years inclusive on the day of informed consent who had not received any GBS vaccine in the past and who received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 - NCT02690181).

Arm type	Experimental
Investigational medicinal product name	Group B Streptococcus Trivalent Glycoconjugate Vaccine
Investigational medicinal product code	
Other name	GBS Trivalent Vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL delivered by the IM route, preferably the deltoid muscle in the non-dominant arm

Number of subjects in period 1	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group
Started	14	14	15
Completed	14	14	15

Number of subjects in period 1	GBS MF59 Full/GBS NoAdj Group	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group
Started	10	6	21
Completed	10	6	21

Baseline characteristics

Reporting groups

Reporting group title	GBS NoAdj/GBS NoAdj Group
Reporting group description: Subjects who had received unadjuvanted GBS Trivalent Vaccine in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).	
Reporting group title	GBS Alum/GBS NoAdj Group
Reporting group description: Subjects who had received GBS Trivalent Vaccine with alum adjuvant in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).	
Reporting group title	GBS MF59 Half/GBS NoAdj Group
Reporting group description: Subjects who had received GBS Trivalent Vaccine with half dose of MF59 in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).	
Reporting group title	GBS MF59 Full/GBS NoAdj Group
Reporting group description: Subjects who had received GBS Trivalent Vaccine with full dose of MF59 in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).	
Reporting group title	Placebo/GBS NoAdj Group
Reporting group description: Subjects who had received placebo in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).	
Reporting group title	Naive/GBS NoAdj Group
Reporting group description: Healthy non-pregnant female subjects aged 22 through 46 years inclusive on the day of informed consent who had not received any GBS vaccine in the past and who received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).	

Reporting group values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group
Number of subjects	14	14	15
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)	0	0	0
Adults (18-64 years)	14	14	15
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	32.4	31.6	28.9
standard deviation	± 6.91	± 6.06	± 4.68

Gender categorical			
Units: Subjects			
Female	14	14	15
Male	0	0	0
Race/Ethnicity, Customized			
Units: Subjects			
White	14	14	15

Reporting group values	GBS MF59 Full/GBS NoAdj Group	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group
Number of subjects	10	6	21
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)	0	0	0
Adults (18-64 years)	10	6	21
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	29.7	28.3	29.2
standard deviation	± 6.22	± 5.39	± 6.96
Gender categorical			
Units: Subjects			
Female	10	6	21
Male	0	0	0
Race/Ethnicity, Customized			
Units: Subjects			
White	10	6	21

Reporting group values	Total		
Number of subjects	80		
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)	80		
From 65-84 years	0		
85 years and over	0		

Age continuous Units: years arithmetic mean standard deviation	-		
Gender categorical Units: Subjects			
Female	80		
Male	0		
Race/Ethnicity, Customized Units: Subjects			
White	80		

End points

End points reporting groups

Reporting group title	GBS NoAdj/GBS NoAdj Group
Reporting group description: Subjects who had received unadjuvanted GBS Trivalent Vaccine in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).	
Reporting group title	GBS Alum/GBS NoAdj Group
Reporting group description: Subjects who had received GBS Trivalent Vaccine with alum adjuvant in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).	
Reporting group title	GBS MF59 Half/GBS NoAdj Group
Reporting group description: Subjects who had received GBS Trivalent Vaccine with half dose of MF59 in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).	
Reporting group title	GBS MF59 Full/GBS NoAdj Group
Reporting group description: Subjects who had received GBS Trivalent Vaccine with full dose of MF59 in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).	
Reporting group title	Placebo/GBS NoAdj Group
Reporting group description: Subjects who had received placebo in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).	
Reporting group title	Naive/GBS NoAdj Group
Reporting group description: Healthy non-pregnant female subjects aged 22 through 46 years inclusive on the day of informed consent who had not received any GBS vaccine in the past and who received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).	

Primary: Percentage of Subjects with ELISA Antibody Concentrations of GBS Serotype Ia above pre-specified thresholds - Day 61

End point title	Percentage of Subjects with ELISA Antibody Concentrations of GBS Serotype Ia above pre-specified thresholds - Day 61 ^[1]
End point description: Percentage of subjects who reach pre-defined sequential serotype-specific serum antibody levels for serotype Ia at Day 61 post-vaccination, as measured by Enzyme-linked immunosorbent Assay (ELISA).	
End point type	Primary
End point timeframe: At Day 61	

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	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	14	15	10
Units: Percentage of subjects				
number (confidence interval 95%)				
≥ 0.1 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 0.2 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 0.5 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 1 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 2 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 3 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	93 (68.1 to 99.83)	90 (55.5 to 99.75)
≥ 5 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	93 (68.1 to 99.83)	90 (55.5 to 99.75)
≥ 8 µg/mL	92 (64 to 99.81)	100 (76.8 to 100)	93 (68.1 to 99.83)	90 (55.5 to 99.75)

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	20		
Units: Percentage of subjects				
number (confidence interval 95%)				
≥ 0.1 µg/mL	100 (47.8 to 100)	100 (83.2 to 100)		
≥ 0.2 µg/mL	100 (47.8 to 100)	95 (75.1 to 99.87)		
≥ 0.5 µg/mL	100 (47.8 to 100)	90 (68.3 to 98.8)		
≥ 1 µg/mL	80 (28.4 to 99.5)	85 (62.1 to 96.8)		
≥ 2 µg/mL	60 (14.7 to 94.7)	65 (40.8 to 84.6)		
≥ 3 µg/mL	60 (14.7 to 94.7)	60 (36.1 to 80.9)		
≥ 5 µg/mL	60 (14.7 to 94.7)	60 (36.1 to 80.9)		
≥ 8 µg/mL	60 (14.7 to 94.7)	60 (36.1 to 80.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects with Antibody Concentrations of GBS Serotype 1b above pre-specified thresholds - Day 61

End point title	Percentage of Subjects with Antibody Concentrations of GBS Serotype Ib above pre-specified thresholds - Day 61 ^[2]
End point description:	
Percentage of subjects who reach pre-defined sequential serotype-specific serum antibody levels for serotype Ib at day 61 post-vaccination. As the singleton ELISA was no longer in use at the time of serotypes Ib and III testing, results for both serotypes were tested using multiplex immunoassay.	
End point type	Primary
End point timeframe:	
At Day 61	

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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	14	15	10
Units: Percentage of subjects				
number (confidence interval 95%)				
≥ 0.1 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 0.2 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 0.5 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 1 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 2 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 3 µg/mL	100 (75.3 to 100)	93 (66.1 to 99.82)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 5 µg/mL	85 (54.6 to 98.1)	93 (66.1 to 99.82)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 8 µg/mL	85 (54.6 to 98.1)	93 (66.1 to 99.82)	93 (68.1 to 99.83)	100 (69.2 to 100)

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	20		
Units: Percentage of subjects				
number (confidence interval 95%)				
≥ 0.1 µg/mL	100 (47.8 to 100)	85 (62.1 to 96.8)		
≥ 0.2 µg/mL	100 (47.8 to 100)	80 (56.3 to 94.3)		
≥ 0.5 µg/mL	80 (28.4 to 99.5)	70 (45.7 to 88.1)		
≥ 1 µg/mL	60 (14.7 to 94.7)	65 (40.8 to 84.6)		
≥ 2 µg/mL	60 (14.7 to 94.7)	50 (27.2 to 72.8)		

≥ 3 µg/mL	60 (14.7 to 94.7)	50 (27.2 to 72.8)		
≥ 5 µg/mL	60 (14.7 to 94.7)	45 (23.1 to 68.5)		
≥ 8 µg/mL	20 (0.5 to 71.6)	40 (19.1 to 63.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of All Subjects with Antibody Concentrations of GBS Serotype III above pre-specified thresholds - Day 61

End point title	Percentage of All Subjects with Antibody Concentrations of GBS Serotype III above pre-specified thresholds - Day 61 ^[3]
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End point description:

Percentage of subjects who reach pre-defined sequential serotype-specific serum antibody levels for serotype III at day 61 post-vaccination. As the singleton ELISA was no longer in use at the time of serotypes Ib and III testing, results for both serotypes were tested using multiplex immunoassay.

End point type	Primary
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End point timeframe:

At Day 61

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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	13	15	10
Units: Percentage of subjects				
number (confidence interval 95%)				
≥ 0.1 µg/mL	100 (75.3 to 100)	100 (75.3 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 0.2 µg/mL	100 (75.3 to 100)	100 (75.3 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 0.5 µg/mL	100 (75.3 to 100)	100 (75.3 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 1 µg/mL	100 (75.3 to 100)	100 (75.3 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 2 µg/mL	100 (75.3 to 100)	100 (75.3 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 3 µg/mL	100 (75.3 to 100)	100 (75.3 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 5 µg/mL	100 (75.3 to 100)	100 (75.3 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 8 µg/mL	100 (75.3 to 100)	92 (64 to 99.81)	100 (78.2 to 100)	100 (69.2 to 100)

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	20		
Units: Percentage of subjects				
number (confidence interval 95%)				
≥ 0.1 µg/mL	100 (47.8 to 100)	100 (83.2 to 100)		
≥ 0.2 µg/mL	100 (47.8 to 100)	80 (56.3 to 94.3)		
≥ 0.5 µg/mL	80 (28.4 to 99.5)	80 (56.3 to 94.3)		
≥ 1 µg/mL	40 (5.3 to 85.3)	75 (50.9 to 91.3)		
≥ 2 µg/mL	40 (5.3 to 85.3)	65 (40.8 to 84.6)		
≥ 3 µg/mL	40 (5.3 to 85.3)	65 (40.8 to 84.6)		
≥ 5 µg/mL	40 (5.3 to 85.3)	50 (27.2 to 72.8)		
≥ 8 µg/mL	40 (5.3 to 85.3)	50 (27.2 to 72.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Numbers of subjects with solicited local and systemic Adverse Events (AEs)

End point title	Numbers of subjects with solicited local and systemic Adverse Events (AEs) ^[4]
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End point description:

Threshold for Erythema, Swelling and Induration: None (0 mm), Any (≥ 1 mm).

End point type	Primary
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End point timeframe:

Day 1 to Day 7

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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	14	15	10
Units: Participants				
Any Local (N=14,14,15,10,5,21)	11	12	10	6
Pain (N=14,14,15,10,5,21)	10	9	9	6
Erythema (N=14,14,15,10,5,21)	1	4	2	1
Swelling (N=14,14,15,10,5,20)	0	2	4	1
Warmth (N=14,14,15,10,5,21)	1	4	4	2
Induration (N=14,14,15,10,5,20)	2	2	5	2

Ecchymosis (N=14,14,15,10,5,20)	0	0	1	0
Any Systemic (N=14,14,15,10,5,21)	5	11	7	5
Chills (N=14,14,15,10,5,21)	0	0	1	1
Nausea (N=14,14,15,10,5,21)	0	2	2	0
Malaise (N=14,14,15,10,5,21)	0	2	2	2
Generalized Myalgia (N=14,14,15,10,5,21)	2	2	2	1
Generalized Arthralgia (N=14,14,15,10,5,21)	0	1	2	0
Headache (N=14,14,15,10,5,21)	4	4	5	2
Fatigue (N=14,14,15,10,5,21)	3	10	4	4
Body Rash (N=14,14,15,10,5,21)	0	1	0	0
Fever ($\geq 38^{\circ}\text{C}$) (N=14,14,15,10,5,21)	0	0	0	0

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	21		
Units: Participants				
Any Local (N=14,14,15,10,5,21)	3	11		
Pain (N=14,14,15,10,5,21)	3	11		
Erythema (N=14,14,15,10,5,21)	1	3		
Swelling (N=14,14,15,10,5,20)	1	0		
Warmth (N=14,14,15,10,5,21)	2	2		
Induration (N=14,14,15,10,5,20)	1	0		
Ecchymosis (N=14,14,15,10,5,20)	0	1		
Any Systemic (N=14,14,15,10,5,21)	2	5		
Chills (N=14,14,15,10,5,21)	1	0		
Nausea (N=14,14,15,10,5,21)	0	1		
Malaise (N=14,14,15,10,5,21)	1	1		
Generalized Myalgia (N=14,14,15,10,5,21)	1	1		
Generalized Arthralgia (N=14,14,15,10,5,21)	0	0		
Headache (N=14,14,15,10,5,21)	2	4		
Fatigue (N=14,14,15,10,5,21)	1	2		
Body Rash (N=14,14,15,10,5,21)	0	0		
Fever ($\geq 38^{\circ}\text{C}$) (N=14,14,15,10,5,21)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any unsolicited Adverse Events (AEs)

End point title	Number of subjects with any unsolicited Adverse Events
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End point description:

The number of subjects with any unsolicited AEs from the day of vaccination in study V98_06E1 to Day 31. An unsolicited adverse event is an adverse event that was not solicited using a Subject Diary and

that was spontaneously communicated by a subject who has signed the informed consent. Potential unsolicited AEs may be medically attended (defined as symptoms or illnesses requiring hospitalization, or emergency room visit, or visit to/by a health care provider), or were of concern to the subject. Possibly Related AE definition: the administration of the investigational vaccine and AE are considered reasonably related in time and the AE could be explained by exposure to the investigational vaccine or by other causes. Probably Related AE definition: exposure to the investigational vaccine and AE are reasonably related in time and no alternative explanation has been identified.

End point type	Primary
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End point timeframe:

Day 1 to Day 31

Notes:

[5] - 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	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	14	15	10
Units: Participants				
Any AE	4	5	4	4
At least possibly or probably related AEs	1	1	0	0

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	21		
Units: Participants				
Any AE	4	9		
At least possibly or probably related AEs	1	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with Serious Adverse Events (SAEs), medically attended AEs, and AEs leading to study withdrawal

End point title	Number of subjects with Serious Adverse Events (SAEs), medically attended AEs, and AEs leading to study withdrawal ^[6]
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End point description:

An SAE is defined as any untoward medical occurrence that at any dose results in one or more of the following: Death; life-threatening; that does not refer to an event which hypothetically might have caused death if it were more severe; required or prolonged hospitalization; persistent or significant disability/incapacity; congenital anomaly/or birth defect; any important and significant medical event that may not be immediately life-threatening or resulting in death or hospitalization but, based upon appropriate medical judgement, may jeopardize the subject or may require intervention to prevent one of the other outcomes listed above. "Medically attended adverse event" is defined as an adverse event that leads to a visit to a healthcare provider and "AEs leading to withdrawal" are defined as adverse events leading to study or vaccine withdrawal.

End point type	Primary
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End point timeframe:

Day 1 to Day 181

Notes:

[6] - 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	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	14	15	10
Units: Participants				
SAEs	0	0	0	0
Medically attended AEs	5	5	7	0
AEs leading to withdrawal	0	0	0	0

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	21		
Units: Participants				
SAEs	0	0		
Medically attended AEs	2	5		
AEs leading to withdrawal	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with ELISA Antibody Concentrations of GBS Serotype Ia above pre-specified thresholds - Day 31

End point title	Percentage of Subjects with ELISA Antibody Concentrations of GBS Serotype Ia above pre-specified thresholds - Day 31
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End point description:

Percentage of subjects who reach pre-defined sequential serotype-specific serum antibody levels for serotype Ia at Day 31 post-vaccination, as measured by ELISA.

End point type	Secondary
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End point timeframe:

At Day 31

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	14	15	10
Units: Percentage of subjects				
number (confidence interval 95%)				
≥ 0.1 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 0.2 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 0.5 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 1 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 2 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 3 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 5 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	93 (68.1 to 99.83)	90 (55.5 to 99.75)
≥ 8 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	93 (68.1 to 99.83)	90 (55.5 to 99.75)

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	20		
Units: Percentage of subjects				
number (confidence interval 95%)				
≥ 0.1 µg/mL	100 (54.1 to 100)	100 (83.2 to 100)		
≥ 0.2 µg/mL	100 (54.1 to 100)	85 (62.1 to 96.8)		
≥ 0.5 µg/mL	100 (54.1 to 100)	80 (56.3 to 94.3)		
≥ 1 µg/mL	83 (35.9 to 99.58)	75 (50.9 to 91.3)		
≥ 2 µg/mL	67 (22.3 to 95.7)	60 (36.1 to 80.9)		
≥ 3 µg/mL	67 (22.3 to 95.7)	60 (36.1 to 80.9)		
≥ 5 µg/mL	67 (22.3 to 95.7)	60 (36.1 to 80.9)		
≥ 8 µg/mL	67 (22.3 to 95.7)	60 (36.1 to 80.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Antibody Concentrations of GBS Serotype 1b above pre-specified thresholds - Day 31

End point title	Percentage of Subjects with Antibody Concentrations of GBS Serotype Ib above pre-specified thresholds - Day 31
End point description:	
Percentage of subjects who reach pre-defined sequential serotype-specific serum antibody levels for serotype Ib at day 31 post-vaccination. As the singleton ELISA was no longer in use at the time of serotypes Ib and III testing, results for both serotypes were tested using multiplex immunoassay.	
End point type	Secondary
End point timeframe:	
At Day 31	

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	14	15	10
Units: Percentage of subjects				
number (confidence interval 95%)				
≥ 0.1 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 0.2 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 0.5 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 1 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 2 µg/mL	100 (75.3 to 100)	100 (76.8 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 3 µg/mL	100 (75.3 to 100)	93 (66.1 to 99.82)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 5 µg/mL	92 (64 to 99.81)	93 (66.1 to 99.82)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 8 µg/mL	85 (54.6 to 98.1)	93 (66.1 to 99.82)	93 (68.1 to 99.83)	100 (69.2 to 100)

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	20		
Units: Percentage of subjects				
number (confidence interval 95%)				
≥ 0.1 µg/mL	100 (54.1 to 100)	75 (50.9 to 91.3)		
≥ 0.2 µg/mL	100 (54.1 to 100)	70 (45.7 to 88.1)		
≥ 0.5 µg/mL	83 (35.9 to 99.58)	60 (36.1 to 80.9)		
≥ 1 µg/mL	83 (35.9 to 99.58)	45 (23.1 to 68.5)		
≥ 2 µg/mL	50 (11.8 to 88.2)	45 (23.1 to 68.5)		
≥ 3 µg/mL	50 (11.8 to 88.2)	45 (23.1 to 68.5)		

≥ 5 µg/mL	50 (11.8 to 88.2)	45 (23.1 to 68.5)		
≥ 8 µg/mL	50 (11.8 to 88.2)	45 (23.1 to 68.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Antibody Concentrations of GBS Serotype III above pre-specified thresholds - Day 31

End point title	Percentage of Subjects with Antibody Concentrations of GBS Serotype III above pre-specified thresholds - Day 31
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End point description:

Percentage of subjects who reach pre-defined sequential serotype-specific serum antibody levels for serotype III at day 31 post-vaccination. As the singleton ELISA was no longer in use at the time of serotypes Ib and III testing, results for both serotypes were tested using multiplex immunoassay.

End point type	Secondary
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End point timeframe:

At Day 31

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	13	15	10
Units: Percentage of subjects				
number (confidence interval 95%)				
≥ 0.1 µg/mL	100 (75.3 to 100)	100 (75.3 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 0.2 µg/mL	100 (75.3 to 100)	100 (75.3 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 0.5 µg/mL	100 (75.3 to 100)	100 (75.3 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 1 µg/mL	100 (75.3 to 100)	100 (75.3 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 2 µg/mL	100 (75.3 to 100)	100 (75.3 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 3 µg/mL	100 (75.3 to 100)	100 (75.3 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 5 µg/mL	100 (75.3 to 100)	100 (75.3 to 100)	100 (78.2 to 100)	100 (69.2 to 100)
≥ 8 µg/mL	100 (75.3 to 100)	92 (64 to 99.81)	100 (78.2 to 100)	100 (69.2 to 100)

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	20		

Units: Percentage of subjects				
number (confidence interval 95%)				
≥ 0.1 µg/mL	100 (54.1 to 100)	100 (83.2 to 100)		
≥ 0.2 µg/mL	67 (22.3 to 95.7)	75 (50.9 to 91.3)		
≥ 0.5 µg/mL	67 (22.3 to 95.7)	70 (45.7 to 88.1)		
≥ 1 µg/mL	50 (11.8 to 88.2)	65 (40.8 to 84.6)		
≥ 2 µg/mL	50 (11.8 to 88.2)	60 (36.1 to 80.9)		
≥ 3 µg/mL	33 (4.3 to 77.7)	55 (31.5 to 76.9)		
≥ 5 µg/mL	33 (4.3 to 77.7)	55 (31.5 to 76.9)		
≥ 8 µg/mL	33 (4.3 to 77.7)	50 (27.2 to 72.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean ELISA Antibody Concentrations of GBS Serotype Ia

End point title	Geometric Mean ELISA Antibody Concentrations of GBS Serotype Ia
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End point description:

The Geometric Mean ELISA Antibody Concentrations of GBS Serotype Ia in All Subjects were estimated for at Day 1, Day 31 and Day 61.

End point type	Secondary
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End point timeframe:

At Day 1, Day 31 and Day 61

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	14	15	10
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype Ia-Day 1(V98_06E1), (N=14;14;15;10;6;20)	9.32 (3.03 to 29)	5.50 (1.79 to 17)	3.44 (1.16 to 10)	2.18 (0.58 to 8.24)
Serotype Ia-Day 31, (N=13;14;15;10;6;20)	61.13 (23 to 165)	81.61 (31 to 213)	64.19 (25 to 162)	57.54 (19 to 179)
Serotype Ia-Day 61, (N=13;14;15;10;5;20)	51.53 (21 to 129)	65.30 (27 to 158)	44.69 (19 to 105)	50.67 (18 to 145)

End point values	Placebo/GBS	Naive/GBS		
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	NoAdj Group	NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	20		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype Ia-Day 1(V98_06E1), (N=14;14;15;10;6;20)	1.05 (0.19 to 5.86)	0.32 (0.13 to 0.83)		
Serotype Ia-Day 31, (N=13;14;15;10;6;20)	19.25 (4.46 to 83)	10.06 (4.52 to 22)		
Serotype Ia-Day 61, (N=13;14;15;10;5;20)	21.36 (4.85 to 94)	10.02 (4.77 to 21)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Antibody Concentrations of GBS Serotype Ib

End point title	Geometric Mean Antibody Concentrations of GBS Serotype Ib
End point description: The Geometric Mean Antibody Concentrations of GBS Serotype Ib in All Subjects were estimated for at Day 1, Day 31 and Day 61. As the singleton ELISA was no longer in use at the time of serotypes Ib and III testing, results for both serotypes were tested using multiplex immunoassay.	
End point type	Secondary
End point timeframe: At Day 1, Day 31 and Day 61	

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	14	15	10
Units: µg/mL				
geometric mean (confidence interval 95%)				
Day 1, (N = 14; 14; 15; 10; 4; 20)	0.19 (0.093 to 0.41)	0.15 (0.073 to 0.32)	0.10 (0.049 to 0.20)	0.16 (0.068 to 0.39)
Day 31, (N = 13; 14; 15; 10; 6; 20)	80.62 (28 to 232)	74.96 (27 to 207)	89.59 (33 to 241)	85.9 (26 to 286)
Day 61, (N = 13; 14; 15; 10; 5; 20)	56.32 (22 to 145)	57.82 (23 to 143)	59.13 (24 to 143)	65.53 (22 to 192)

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	20		
Units: µg/mL				
geometric mean (confidence interval				

95%)				
Day 1, (N = 14; 14; 15; 10; 4; 20)	0.14 (0.035 to 0.55)	0.17 (0.093 to 0.32)		
Day 31, (N = 13; 14; 15; 10; 6; 20)	6.61 (0.99 to 44)	3.55 (1.52 to 8.34)		
Day 61, (N = 13; 14; 15; 10; 5; 20)	5.51 (1.01 to 30)	4.47 (2.09 to 9.58)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Antibody Concentrations of GBS Serotype III

End point title	Geometric Mean Antibody Concentrations of GBS Serotype III
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End point description:

The Geometric Mean Antibody Concentrations of GBS Serotype III in All Subjects were estimated for at Day 1, Day 31 and Day 61. As the singleton ELISA was no longer in use at the time of serotypes Ib and III testing, results for both serotypes were tested using multiplex immunoassay.

End point type	Secondary
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End point timeframe:

At Day 1, Day 31 and Day 61

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	13	15	10
Units: µg/mL				
geometric mean (confidence interval 95%)				
Day 1, (N = 14; 13; 15; 10; 4; 20)	0.41 (0.20 to 0.82)	0.17 (0.085 to 0.36)	0.25 (0.13 to 0.49)	0.17 (0.076 to 0.39)
Day 31, (N = 13; 13; 15; 10; 6; 20)	111.3 (42 to 294)	104.55 (40 to 277)	109.23 (44 to 269)	216.39 (71 to 655)
Day 61, (N = 13; 13; 15; 10; 5; 20)	91.3 (39 to 214)	80.94 (34 to 190)	81.71 (37 to 180)	200.78 (76 to 531)

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	20		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Day 1, (N = 14; 13; 15; 10; 4; 20)	0.15 (0.040 to 0.54)	0.31 (0.17 to 0.55)		
Day 31, (N = 13; 13; 15; 10; 6; 20)	2.66 (0.46 to 15)	5.33 (2.43 to 12)		

Day 61, (N = 13; 13; 15; 10; 5; 20)	2.67 (0.57 to 12)	5.82 (2.92 to 12)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean ELISA Antibody Concentrations of GBS Serotype Ia in subjects with prevaccination serotype-specific GBS antibody less than the Lower Limit of Quantitation (LLQ)

End point title	Geometric Mean ELISA Antibody Concentrations of GBS Serotype Ia in subjects with prevaccination serotype-specific GBS antibody less than the Lower Limit of Quantitation (LLQ)
End point description: The Geometric Mean ELISA Antibody Concentrations of GBS Serotype Ia in subjects with prevaccination serotype-specific GBS antibody less than LLQ, were estimated for at Day 1, Day 31 and Day 61.	
End point type	Secondary
End point timeframe: At Day 1, Day 31 and Day 61	

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	10	9	7
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype Ia-Day 1 (V98_06E1), (N=7;10;9;7;4;15)	1.36 (0.43 to 4.27)	2.59 (0.99 to 6.75)	0.81 (0.30 to 2.24)	1.12 (0.36 to 3.52)
Serotype Ia-Day 31, (N=7;10;9;7;4;15)	32.25 (8.59 to 121)	62.54 (21 to 189)	35.47 (11 to 114)	46.11 (12 to 173)
Serotype Ia-Day 61, (N=7;10;9;7;3;15)	26.33 (8.12 to 85)	49.01 (18 to 131)	24.89 (8.82 to 70)	39.56 (12 to 128)

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	15		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype Ia-Day 1 (V98_06E1), (N=7;10;9;7;4;15)	0.45 (0.099 to 2.05)	0.16 (0.074 to 0.36)		
Serotype Ia-Day 31, (N=7;10;9;7;4;15)	6.34 (1.10 to 36)	3.98 (1.61 to 9.84)		

Serotype Ia-Day 61, (N=7;10;9;7;3;15)	5.79 (0.96 to 35)	4.25 (1.90 to 9.48)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Antibody Concentrations of GBS Serotype Ib in subjects with prevaccination serotype-specific GBS antibody less than LLQ

End point title	Geometric Mean Antibody Concentrations of GBS Serotype Ib in subjects with prevaccination serotype-specific GBS antibody less than LLQ
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End point description:

The Geometric Mean Antibody Concentrations of GBS Serotype Ib in subjects with prevaccination serotype-specific GBS antibody less than LLQ, were estimated for at Day 1, Day 31 and Day 61. As the singleton ELISA was no longer in use at the time of serotypes Ib and III testing, results for both serotypes were tested using multiplex immunoassay.

End point type	Secondary
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End point timeframe:

At Day 1, Day 31 and Day 61

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	9	14	8
Units: µg/mL				
geometric mean (confidence interval 95%)				
Day 1	0.078 (0.078 to 0.078)	0.078 (0.078 to 0.078)	0.078 (0.078 to 0.078)	0.078 (0.078 to 0.078)
Day 31	60.78 (20 to 182)	69.05 (22 to 220)	53.01 (21 to 134)	65.50 (19 to 224)
Day 61	40.59 (15 to 111)	47.71 (16 to 138)	34.12 (15 to 80)	47.58 (15 to 147)

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	15		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Day 1	0.078 (0.078 to 0.078)	0.078 (0.078 to 0.078)		
Day 31	1.47 (0.2 to 11)	0.79 (0.32 to 1.95)		

Day 61	1.32 (0.21 to 8.37)	1.19 (0.52 to 2.71)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Antibody Concentrations of GBS Serotype III in subjects with prevaccination serotype-specific GBS antibody less than LLQ

End point title	Geometric Mean Antibody Concentrations of GBS Serotype III in subjects with prevaccination serotype-specific GBS antibody less than LLQ
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End point description:

The Geometric Mean Antibody Concentrations of GBS Serotype III in subjects with prevaccination serotype-specific GBS antibody less than LLQ, were estimated for at Day 1, Day 31 and Day 61. As the singleton ELISA was no longer in use at the time of serotypes Ib and III testing, results for both serotypes were tested using multiplex immunoassay.

End point type	Secondary
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End point timeframe:

At Day 1, Day 31 and Day 61

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	12	11	9
Units: µg/mL				
geometric mean (confidence interval 95%)				
Day 1	0.15 (0.15 to 0.15)	0.15 (0.15 to 0.15)	0.15 (0.15 to 0.15)	0.15 (0.15 to 0.15)
Day 31	109.31 (40 to 301)	77.97 (31 to 197)	126.89 (48 to 333)	188.63 (65 to 549)
Day 61	83.19 (33 to 208)	60.01 (26 to 138)	87.4 (37 to 209)	169.45 (65 to 444)

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	15		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Day 1	0.15 (0.15 to 0.15)	0.15 (0.15 to 0.15)		
Day 31	1.9 (0.38 to 9.44)	2.12 (0.93 to 4.84)		

Day 61	1.92 (0.45 to 8.16)	2.52 (1.2 to 5.32)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean ELISA Antibody Concentrations of GBS Serotype Ia in subjects with prevaccination serotype-specific GBS antibody equal or greater than LLQ

End point title	Geometric Mean ELISA Antibody Concentrations of GBS Serotype Ia in subjects with prevaccination serotype-specific GBS antibody equal or greater than LLQ
End point description: The Geometric Mean ELISA Antibody Concentrations of GBS Serotype Ia in subjects with prevaccination serotype-specific GBS antibody equal or greater than LLQ, were estimated for at Day 1, Day 31 and Day 61.	
End point type	Secondary
End point timeframe: At Day 1, Day 31 and Day 61	

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	6	2
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype Ia - Day 1 (V98_06E1), (N=7;3;6;2;2;5)	64.06 (23 to 178)	98.43 (21 to 469)	29.83 (9.89 to 90)	39.57 (5.84 to 268)
Serotype Ia - Day 31, (N=6;3;6;2;2;5)	128.91 (71 to 234)	196.32 (85 to 456)	156.26 (86 to 284)	85.63 (31 to 240)
Serotype Ia - Day 61, (N=6;3;6;2;2;5)	112.78 (57 to 222)	197.67 (76 to 515)	107.57 (55 to 212)	93.02 (29 to 300)

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	5		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype Ia - Day 1 (V98_06E1), (N=7;3;6;2;2;5)	5.76 (0.85 to 39)	2.54 (0.76 to 8.50)		
Serotype Ia - Day 31, (N=6;3;6;2;2;5)	177.38 (63 to 498)	161.99 (84 to 311)		

Serotype Ia - Day 61, (N=6;3;6;2;2;5)	151.27 (47 to 488)	131.48 (63 to 276)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Antibody Concentrations of GBS Serotype Ib in subjects with prevaccination serotype-specific GBS antibody equal or greater than LLQ

End point title	Geometric Mean Antibody Concentrations of GBS Serotype Ib in subjects with prevaccination serotype-specific GBS antibody equal or greater than LLQ
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End point description:

The Geometric Mean Antibody Concentrations of GBS Serotype Ib in subjects with prevaccination serotype-specific GBS antibody equal or greater than LLQ, were estimated for at Day 1, Day 31 and Day 61. As the singleton ELISA was no longer in use at the time of serotypes Ib and III testing, results for both serotypes were tested using multiplex immunoassay.

End point type	Secondary
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End point timeframe:

At Day 1, Day 31 and Day 61

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	1	2
Units: µg/mL				
geometric mean (confidence interval 95%)				
Day 1, (N = 4; 5; 1; 2; 1; 5)	1.96 (0.56 to 6.85)	0.52 (0.17 to 1.6)	3.42 (0.28 to 42)	3.12 (0.53 to 18)
Day 31, (N = 3; 5; 1; 2; 1; 5)	287.34 (90 to 917)	121.6 (44 to 333)	373.02 (48 to 2877)	338.8 (78 to 1469)
Day 61, (N = 4; 5; 1; 2; 1; 5)	228.26 (72 to 726)	118.94 (43 to 326)	367.26 (48 to 2818)	300.1 (69 to 1296)

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	5		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Day 1, (N = 4; 5; 1; 2; 1; 5)	0.82 (0.067 to 10)	1.92 (0.63 to 5.89)		
Day 31, (N = 3; 5; 1; 2; 1; 5)	557.46 (75 to 4142)	557.03 (225 to 1379)		

Day 61, (N = 4; 5; 1; 2; 1; 5)	378.7 (51 to 2800)	403.16 (163 to 996)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Antibody Concentrations of GBS Serotype III in subjects with prevaccination serotype-specific GBS antibody equal or greater than LLQ

End point title	Geometric Mean Antibody Concentrations of GBS Serotype III in subjects with prevaccination serotype-specific GBS antibody equal or greater than LLQ
End point description:	The Geometric Mean Antibody Concentrations of GBS Serotype III in subjects with prevaccination serotype-specific GBS antibody equal or greater than LLQ, were estimated for at Day 1, Day 31 and Day 61. As the singleton ELISA was no longer in use at the time of serotypes Ib and III testing, results for both serotypes were tested using multiplex immunoassay.
End point type	Secondary
End point timeframe:	At Day 1, Day 31 and Day 61

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	1	4	1
Units: µg/mL				
geometric mean (confidence interval 95%)				
Day 1, (N = 4; 1; 4; 1; 0; 5)	5.33 (0.76 to 37)	1.41 (0.029 to 68)	1.07 (0.15 to 7.46)	0.74 (0.015 to 36)
Day 31, (N = 3; 1; 4; 1; 0; 5)	171.67 (13 to 2214)	270.01 (3.46 to 21064)	120.0 (13 to 1113)	149.93 (1.81 to 12454)
Day 61, (N = 3; 1; 4; 1; 0; 5)	186.63 (24 to 1439)	231.17 (7.12 to 7509)	107.21 (18 to 635)	180.29 (5.28 to 6158)

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[7]	5		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Day 1, (N = 4; 1; 4; 1; 0; 5)	(to)	2.79 (0.49 to 16)		
Day 31, (N = 3; 1; 4; 1; 0; 5)	(to)	136.68 (19 to 979)		

Day 61, (N = 3; 1; 4; 1; 0; 5)	(to)	116.43 (24 to 561)		
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Notes:

[7] - No participants analyzed in this group

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean ELISA Anti-Diphtheria Antibody Concentrations in All Subjects

End point title	Geometric Mean ELISA Anti-Diphtheria Antibody Concentrations in All Subjects
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End point description:

Geometric Mean ELISA Anti-Diphtheria Antibody Concentrations (95%CI) in All Subjects at Day 1 Pre-vaccination in the V98_06 study or V98_06E1 for the Naive Group and at Day 61 Post-vaccination in Study V98_06E1. Anti-diphtheria antibody testing was not performed in this study because no diphtheria vaccine was administered in the study and also because data from other Cross Reactive Material(CRM)-based vaccines demonstrate that administration has not resulted in a decline in anti-diphtheria antibody concentrations.

End point type	Secondary
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End point timeframe:

At Day 1 (V98_06 or V98_06E1) and Day 61

End point values	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group	GBS MF59 Full/GBS NoAdj Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[8]	0 ^[9]	0 ^[10]	0 ^[11]
Units: µg/mL				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[8] - Analysis was not performed.

[9] - Analysis was not performed.

[10] - Analysis was not performed.

[11] - Analysis was not performed.

End point values	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[12]	0 ^[13]		
Units: µg/mL				
geometric mean (confidence interval 95%)	(to)	(to)		

Notes:

[12] - Analysis was not performed.

[13] - Analysis was not performed.

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs were collected until 7 days after vaccination. Unsolicited AEs were collected from Day 1 to Day 181. SAEs were collected from Day 1 to Day 181.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.1
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Reporting groups

Reporting group title	GBS NoAdj/GBS NoAdj Group
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Reporting group description:

Subjects who had received unadjuvanted GBS Trivalent Vaccine in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).

Reporting group title	GBS Alum/GBS NoAdj Group
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Reporting group description:

Subjects who had received GBS Trivalent Vaccine with alum adjuvant in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).

Reporting group title	GBS MF59 Half/GBS NoAdj Group
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Reporting group description:

Subjects who had received GBS Trivalent Vaccine with half dose of MF59 in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).

Reporting group title	GBS MF59 Full/GBS NoAdj Group
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Reporting group description:

Subjects who had received GBS Trivalent Vaccine with full dose of MF59 in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).

Reporting group title	Placebo/GBS NoAdj Group
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Reporting group description:

Subjects who had received placebo in parent study V98_06 (205468 – NCT01150123) and received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).

Reporting group title	Naive/GBS NoAdj Group
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Reporting group description:

Healthy non-pregnant female subjects aged 22 through 46 years inclusive on the day of informed consent who had not received any GBS vaccine in the past and who received a single dose of unadjuvanted GBS Trivalent Vaccine in V98_06E1 (205421 – NCT02690181).

Serious adverse events	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	GBS MF59 Full/GBS	Placebo/GBS NoAdj	Naive/GBS NoAdj
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	NoAdj Group	Group	Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

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

Non-serious adverse events	GBS NoAdj/GBS NoAdj Group	GBS Alum/GBS NoAdj Group	GBS MF59 Half/GBS NoAdj Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 14 (92.86%)	13 / 14 (92.86%)	13 / 15 (86.67%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	3 / 14 (21.43%)	10 / 14 (71.43%)	4 / 15 (26.67%)
occurrences (all)	11	13	9
Feeling hot			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Injection site erythema			
subjects affected / exposed	1 / 14 (7.14%)	4 / 14 (28.57%)	2 / 15 (13.33%)
occurrences (all)	3	6	2
Injection site haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	3
Injection site induration			

subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 3	2 / 14 (14.29%) 3	5 / 15 (33.33%) 10
Injection site pain subjects affected / exposed occurrences (all)	10 / 14 (71.43%) 20	9 / 14 (64.29%) 15	9 / 15 (60.00%) 19
Injection site swelling subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	2 / 14 (14.29%) 3	4 / 15 (26.67%) 6
Injection site warmth subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 2	4 / 14 (28.57%) 5	4 / 15 (26.67%) 7
Malaise subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	2 / 14 (14.29%) 3	2 / 15 (13.33%) 3
Hangover subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Immune system disorders Allergy to arthropod bite subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 14 (7.14%) 1	0 / 15 (0.00%) 0
Reproductive system and breast disorders Vulvovaginal discomfort subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Nasal congestion subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Injury, poisoning and procedural complications Laceration			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Procedural pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Stress fracture subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 14 (7.14%) 1	0 / 15 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	5 / 14 (35.71%) 12	6 / 14 (42.86%) 12	5 / 15 (33.33%) 9
Ear and labyrinth disorders Ear disorder subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Tinnitus subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Eye disorders Conjunctival irritation subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	1 / 15 (6.67%) 1
Eye irritation subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	1 / 15 (6.67%) 1
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 14 (7.14%) 1	0 / 15 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 14 (7.14%) 1	0 / 15 (0.00%) 0
Gastric disorder			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	3 / 14 (21.43%) 4	2 / 15 (13.33%) 3
Tongue ulceration subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Skin and subcutaneous tissue disorders			
Rash subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 14 (7.14%) 1	0 / 15 (0.00%) 0
Rash macular subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 14 (7.14%) 1	0 / 15 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 14 (7.14%) 1	2 / 15 (13.33%) 2
Back pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	1 / 15 (6.67%) 1
Intervertebral disc protrusion subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 4	2 / 14 (14.29%) 3	3 / 15 (20.00%) 4
Tendonitis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 14 (7.14%) 1	0 / 15 (0.00%) 0
Infections and infestations			

Chlamydial infection subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	1 / 15 (6.67%) 1
Gastroenteritis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 14 (7.14%) 1	1 / 15 (6.67%) 1
Sinusitis subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Sinusitis bacterial subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	1 / 15 (6.67%) 1
Tonsillitis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	1 / 15 (6.67%) 1
Tooth infection subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	1 / 15 (6.67%) 1
Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 14 (0.00%) 0	1 / 15 (6.67%) 1
Gingivitis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Rhinitis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0

Non-serious adverse events	GBS MF59 Full/GBS NoAdj Group	Placebo/GBS NoAdj Group	Naive/GBS NoAdj Group
Total subjects affected by non-serious adverse events subjects affected / exposed	7 / 10 (70.00%)	4 / 6 (66.67%)	17 / 21 (80.95%)
Vascular disorders Hot flush subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
General disorders and administration site conditions			

Chills			
subjects affected / exposed	1 / 10 (10.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Fatigue			
subjects affected / exposed	4 / 10 (40.00%)	1 / 6 (16.67%)	2 / 21 (9.52%)
occurrences (all)	6	3	2
Feeling hot			
subjects affected / exposed	1 / 10 (10.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	1 / 10 (10.00%)	1 / 6 (16.67%)	3 / 21 (14.29%)
occurrences (all)	1	8	5
Injection site haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	3
Injection site induration			
subjects affected / exposed	2 / 10 (20.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	6	5	0
Injection site pain			
subjects affected / exposed	6 / 10 (60.00%)	3 / 6 (50.00%)	11 / 21 (52.38%)
occurrences (all)	10	12	23
Injection site swelling			
subjects affected / exposed	1 / 10 (10.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	3	5	0
Injection site warmth			
subjects affected / exposed	2 / 10 (20.00%)	2 / 6 (33.33%)	2 / 21 (9.52%)
occurrences (all)	3	8	2
Malaise			
subjects affected / exposed	2 / 10 (20.00%)	1 / 6 (16.67%)	1 / 21 (4.76%)
occurrences (all)	3	1	1
Hangover			
subjects affected / exposed	0 / 10 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1

Immune system disorders Allergy to arthropod bite subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Reproductive system and breast disorders Vulvovaginal discomfort subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 6 (16.67%) 1	0 / 21 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all) Nasal congestion subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1 0 / 10 (0.00%) 0	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0	2 / 21 (9.52%) 2 1 / 21 (4.76%) 1
Injury, poisoning and procedural complications Laceration subjects affected / exposed occurrences (all) Procedural pain subjects affected / exposed occurrences (all) Stress fracture subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0 0 / 10 (0.00%) 0 0 / 10 (0.00%) 0	1 / 6 (16.67%) 1 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0	0 / 21 (0.00%) 0 2 / 21 (9.52%) 2 0 / 21 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0 3 / 10 (30.00%) 3	0 / 6 (0.00%) 0 2 / 6 (33.33%) 4	0 / 21 (0.00%) 0 4 / 21 (19.05%) 6
Ear and labyrinth disorders Ear disorder subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0

Tinnitus subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Eye disorders Conjunctival irritation subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Eye irritation subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Gastric disorder subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 6 (16.67%) 1	0 / 21 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Tongue ulceration subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Rash macular subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 6 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Intervertebral disc protrusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 10 (10.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Myalgia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 6 (16.67%)	1 / 21 (4.76%)
occurrences (all)	1	1	1
Tendonitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Infections and infestations			
Chlamydial infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Sinusitis bacterial			
subjects affected / exposed	0 / 10 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 6 (0.00%) 0	3 / 21 (14.29%) 3
Gingivitis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Rhinitis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1

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