Clinical trial results:
A Phase II, Randomized, Comparative, Observer-Blind, Multi-Center Study Evaluating the Safety and Immunogenicity of the Liquid Formulation of Group B Streptococcus Trivalent Vaccine and of the Lyophilized Formulation of Group B Streptococcus Trivalent Vaccine in Healthy Non-Pregnant Women aged 18 to 40 Years.

Summary

EudraCT number	2013-003111-22
Trial protocol	BE CZ
Global end of trial date	04 May 2016

Results information

Result version number	v3 (current)
This version publication date	18 December 2019
First version publication date	05 October 2016
Version creation reason	• New data added to full data set Update with Serotype Ib results

Trial information

Trial identification

Sponsor protocol code	205220

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02270944
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, 1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, +44 20899 4466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, +44 20899 4466, 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	06 September 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 May 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Immunogenicity Objectives:
To demonstrate the equivalence of the liquid GBS trivalent vaccine formulation to the lyophilized GBS trivalent vaccine formulation for serotypes Ia, Ib, and III, when administered to healthy non-pregnant women, as measured by Geometric Mean Concentrations (GMCs) at 30 days (Day 31) after a single vaccination.

Safety Objectives:
To evaluate the safety and tolerability of a single dose of liquid and lyophilized GBS trivalent vaccine formulations when administered to healthy non-pregnant women aged 18-40 years.

Protection of trial subjects:

This clinical study was designed, implemented and reported in accordance with the ICH Harmonized Tripartite Guidelines for GCP, with applicable local regulations, including the European Directive 2001/20/EC, the US CFR Title 21, and the Japanese Ministry of Health, Labor, and Welfare, 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	20 November 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	Belgium: 500
Country: Number of subjects enrolled	Czech Republic: 300
Country: Number of subjects enrolled	United States: 253
Worldwide total number of subjects	1053
EEA total number of subjects	800

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)	1053
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

1053 subjects were enrolled at Belgium, US and Czech Republic sites.

Pre-assignment

Screening details:

1053 subjects were enrolled in the study. 1 subject in the Liquid GBS trivalent vaccine Group and 2 subjects in the Lyophilized GBS trivalent vaccine Group were randomized but didn't receive the vaccine.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Liquid GBS trivalent vaccine

Arm description:

Healthy non-pregnant women aged 18-40 years that received a single dose of liquid GBS trivalent vaccine.

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

Dosage and administration details:

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

Arm title	Lyophilized GBS trivalent vaccine

Arm description:

Healthy non-pregnant women aged 18-40 years that received a single dose of lyophilized GBS trivalent vaccine.

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

Dosage and administration details:

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

Number of subjects in period 1[1]	Liquid GBS trivalent vaccine	Lyophilized GBS trivalent vaccine
Started	529	521
Completed	518	516
Not completed	11	5
Consent withdrawn by subject	2	1
Lost to follow-up	9	4

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 1053 Subjects were enrolled in the study. 1 subject in the Liquid GBS trivalent vaccine Group and 2 subjects in the Lyophilized GBS trivalent vaccine Group were randomized but didn't receive the vaccine .

Baseline characteristics

Reporting groups

Reporting group title	Liquid GBS trivalent vaccine
Reporting group description:	
Healthy non-pregnant women aged 18-40 years that received a single dose of liquid GBS trivalent vaccine.	
Reporting group title	Lyophilized GBS trivalent vaccine
Reporting group description:	
Healthy non-pregnant women aged 18-40 years that received a single dose of lyophilized GBS trivalent vaccine.	

Reporting group values	Liquid GBS trivalent vaccine	Lyophilized GBS trivalent vaccine	Total
Number of subjects	529	521	1050
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
arithmetic mean	27.1	27.4	
standard deviation	± 6.24	± 6.05	-
Gender categorical			
Units: Subjects			
Female	529	521	1050
Male	0	0	0

Subject analysis sets

Subject analysis set title	Exposed Set
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
All subjects in the enrolled population who received a study vaccination.	
Subject analysis set title	Full Analysis Set (FAS)
Subject analysis set type	Full analysis
Subject analysis set description:	
All subjects in the enrolled population who: - Received a study vaccination - Provided at least 1 evaluable serum sample both before and after vaccination (both are required as the primary model is an ANCOVA which incorporates baseline concentrations). FAS populations were to be analyzed "as randomized" (ie, according to the vaccine a subject was designated to receive, which may be different from the vaccine the subject actually received).	

Subject analysis set title	Per Protocol Set (PPS)
Subject analysis set type	Per protocol

Subject analysis set description:

All subjects in the FAS immunogenicity population who:
- Correctly received the study vaccine (i.e., received the vaccine to which the subjects were randomized and received the vaccine at the scheduled time point).
- Have no major protocol deviation or other reasons to be excluded, (see section 7.3.8), as defined prior to unblinding.
- Provided evaluable serum samples both before vaccination and at day 31 in the protocol required windows.

Subject analysis set title	Safety Set (solicited AEs and other signs of reactogenicity)
Subject analysis set type	Safety analysis

Subject analysis set description:

All subjects in the exposed set who provided data on post vaccination local or systemic AEs or other signs of reactogenicity.

Subject analysis set title	Safety Set (unsolicited AEs)
Subject analysis set type	Safety analysis

Subject analysis set description:

All subjects in the exposed set who provided information about post-vaccination unsolicited AEs.

Subject analysis set title	Safety Set (overall)
Subject analysis set type	Safety analysis

Subject analysis set description:

All subjects in the exposed set who have either provided data on post-vaccination AEs or local or systemic AEs or other signs of reactogenicity.

Reporting group values	Exposed Set	Full Analysis Set (FAS)	Per Protocol Set (PPS)
Number of subjects	1050	1043	1034
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean		27.2	27.2
standard deviation	±	± 6.15	± 6.15
Gender categorical Units: Subjects			
Female	1050	1043	1034
Male	0	0	0

Reporting group values	Safety Set (solicited AEs and other signs of reactogenicity)	Safety Set (unsolicited AEs)	Safety Set (overall)
Number of subjects	1050	1047	1047

Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean			27.2
standard deviation	±	±	± 6.14
Gender categorical Units: Subjects			
Female	1050	1047	1047
Male	0	0	0

End points

End points reporting groups

Reporting group title	Liquid GBS trivalent vaccine
Reporting group description:	
Healthy non-pregnant women aged 18-40 years that received a single dose of liquid GBS trivalent vaccine.	
Reporting group title	Lyophilized GBS trivalent vaccine
Reporting group description:	
Healthy non-pregnant women aged 18-40 years that received a single dose of lyophilized GBS trivalent vaccine.	
Subject analysis set title	Exposed Set
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
All subjects in the enrolled population who received a study vaccination.	
Subject analysis set title	Full Analysis Set (FAS)
Subject analysis set type	Full analysis
Subject analysis set description:	
All subjects in the enrolled population who: - Received a study vaccination - Provided at least 1 evaluable serum sample both before and after vaccination (both are required as the primary model is an ANCOVA which incorporates baseline concentrations). FAS populations were to be analyzed "as randomized" (ie, according to the vaccine a subject was designated to receive, which may be different from the vaccine the subject actually received).	
Subject analysis set title	Per Protocol Set (PPS)
Subject analysis set type	Per protocol
Subject analysis set description:	
All subjects in the FAS immunogenicity population who: - Correctly received the study vaccine (i.e., received the vaccine to which the subjects were randomized and received the vaccine at the scheduled time point). - Have no major protocol deviation or other reasons to be excluded, (see section 7.3.8), as defined prior to unblinding. - Provided evaluable serum samples both before vaccination and at day 31 in the protocol required windows.	
Subject analysis set title	Safety Set (solicited AEs and other signs of reactogenicity)
Subject analysis set type	Safety analysis
Subject analysis set description:	
All subjects in the exposed set who provided data on post vaccination local or systemic AEs or other signs of reactogenicity.	
Subject analysis set title	Safety Set (unsolicited AEs)
Subject analysis set type	Safety analysis
Subject analysis set description:	
All subjects in the exposed set who provided information about post-vaccination unsolicited AEs.	
Subject analysis set title	Safety Set (overall)
Subject analysis set type	Safety analysis
Subject analysis set description:	
All subjects in the exposed set who have either provided data on post-vaccination AEs or local or systemic AEs or other signs of reactogenicity.	

Primary: Concentration of serotype Ia GBS IgG levels in healthy non-pregnant women

End point title	Concentration of serotype Ia GBS IgG levels in healthy non-pregnant women
End point description:	
To evaluate serotype-specific Ia GBS serum IgG antibody levels (anti-Ia) in healthy non-pregnant	

women when administered with the liquid GBS trivalent vaccine formulation or the lyophilized GBS trivalent vaccine formulation. Antibody concentrations were measured by Enzyme-linked immunosorbent assay (ELISA), expressed as geometric mean concentrations (GMCs), in micrograms per milliliter (µg/mL).

End point type	Primary

End point timeframe:

Day 31 after a single vaccination

End point values	Liquid GBS trivalent vaccine	Lyophilized GBS trivalent vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	521	513		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serogroup Ia	6.81 (5.54 to 8.37)	6.66 (5.4 to 8.21)		

Statistical analyses

Statistical analysis title	Ratio of GMCs for anti-GBS Ia concentration

Statistical analysis description:

To demonstrate the equivalence of the liquid GBS trivalent vaccine formulation to the lyophilized GBS trivalent vaccine formulation for serotypes Ia when adm inistered to healthy non-pregnant women, as measured by geometric mean concentrations (GMC).

Comparison groups	Lyophilized GBS trivalent vaccine v Liquid GBS trivalent vaccine
Number of subjects included in analysis	1034
Analysis specification	Pre-specified
Analysis type	equivalence[1]
Parameter estimate	Ratio of GMCs
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.32

Notes:

[1] - To assess the vaccine formulations equivalence, the lower limit of the two-sided 95% confidence interval (CI) for the ratio of GMCs at Day 31 after vaccination must be > 0.5 and the upper limit of the two-sided 95% CI must be < 2.0 (the entire two-sided 95% CI must be contained in the 0.5, 2.0 interval). Analysis of covariance (ANCOVA) model with vaccine group and center as fixed effects and log10-prevaccination antibody concentration as a covariate

Primary: Concentration of serotype III GBS IgG levels in healthy non-pregnant women

End point title	Concentration of serotype III GBS IgG levels in healthy non-pregnant women

End point description:

To evaluate serotype-specific III GBS serum IgG antibody levels (anti-III) in healthy non-pregnant women when administered with the liquid GBS trivalent vaccine formulation or the lyophilized GBS trivalent vaccine formulation. Antibody concentrations were measured by Enzyme-linked immunosorbent

assay (ELISA), expressed as geometric mean concentrations (GMCs), in micrograms per milliliter (µg/mL).

End point type	Primary

End point timeframe:

At Day 31 after a single vaccination

End point values	Liquid GBS trivalent vaccine	Lyophilized GBS trivalent vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	492	489		
Units: µg/mL				
geometric mean (confidence interval 95%)	2.42 (1.95 to 3.01)	2.44 (1.95 to 3.04)		

Statistical analyses

Statistical analysis title	Ratio of GMCs for anti-GBS III concentration

Statistical analysis description:

To demonstrate the equivalence of the liquid GBS trivalent vaccine formulation to the lyophilized GBS trivalent vaccine formulation for serotypes III when adm inistered to healthy non-pregnant women, as measured by geometric mean concentrations (GMC).

Comparison groups	Liquid GBS trivalent vaccine v Lyophilized GBS trivalent vaccine
Number of subjects included in analysis	981
Analysis specification	Pre-specified
Analysis type	equivalence[2]
Parameter estimate	Ratio of GMCs
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.3

Notes:

[2] - To assess the vaccine formulations equivalence, the lower limit of the two-sided 95% confidence interval (CI) for the ratio of GMCs at Day 31 after vaccination must be > 0.5 and the upper limit of the two-sided 95% CI must be < 2.0 (the entire two-sided 95% CI must be contained in the 0.5, 2.0 interval). Analysis of covariance (ANCOVA) model with vaccine group and center as fixed effects and log10-prevaccination antibody concentration as a covariate.

Primary: Concentration of serotype Ib GBS IgG levels in healthy non-pregnant women

End point title	Concentration of serotype Ib GBS IgG levels in healthy non-pregnant women

End point description:

To evaluate serotype-specific Ib GBS serum IgG antibody levels (anti-Ib) in healthy nonpregnant women when administered with the liquid GBS trivalent vaccine formulation or the lyophilized GBS trivalent vaccine formulation. Geometric mean concentrations (GMCs) were measured and expressed in micrograms per milliliter (µg/mL). As the singleton ELISA was no longer in use at the time of serotype Ib testing, results were obtained using multiplex immunoassay.

End point type	Primary

End point timeframe:

At Day 31 after a single vaccination

End point values	Liquid GBS trivalent vaccine	Lyophilized GBS trivalent vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	483	470		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype Ib	2.94 (2.37 to 3.65)	3.14 (2.53 to 3.90)		

Statistical analyses

Statistical analysis title	Ratio of GMCs for anti-GBS Ib concentration

Statistical analysis description:

To demonstrate the equivalence of the liquid GBS trivalent vaccine formulation to the lyophilized GBS trivalent vaccine formulation for
serotypes Ib when administered to healthy non-pregnant women, as measured by geometric mean concentrations (GMC).

Comparison groups	Liquid GBS trivalent vaccine v Lyophilized GBS trivalent vaccine
Number of subjects included in analysis	953
Analysis specification	Pre-specified
Analysis type	equivalence[3]
Parameter estimate	Ratio of GMCs
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.22

Notes:

[3] - To assess the vaccine formulations equivalence, the lower limit of the two-sided 95% confidence interval (CI) for the ratio of GMCs at Day 31 after vaccination must be > 0.5 and the upper limit of the two-sided 95% CI must be < 2.0 (the entire two-sided 95% CI must be contained in the 0.5, 2.0 interval). Analysis of covariance (ANCOVA) model with vaccine group and center as fixed effects and log10-prevaccination antibody concentration as a covariate.

Secondary: Number of subjects reporting solicited local and systemic Adverse Events (AEs)

End point title	Number of subjects reporting solicited local and systemic Adverse Events (AEs)

End point description:

Safety was assessed as the number of subjects who reported solicited local and solicited systemic AEs following a single injection with either liquid or lyophilized GBS trivalent vaccine formulations.

End point type	Secondary

End point timeframe:

From 6 hours through Day 7 post-vaccination

End point values	Liquid GBS trivalent vaccine	Lyophilized GBS trivalent vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	524	519		
Units: Subjects				
Any local AEs (N=524;519)	247	229		
Injection site Pain (N=520;518)	227	205		
Injection site Erythema (N=522;518)	16	9		
Injection site Swelling (N=522;519)	12	5		
Injection site Warmth (N=521;517)	68	57		
Injection site Induration (N=521;519)	17	15		
Injection site Ecchymosis (N=520;519)	1	6		
Any Systemic AEs (N=524;519)	280	278		
Chills (N=519;517)	64	56		
Myalgia (N=519;519)	75	78		
Malaise (N=519;519)	104	103		
Nausea (N=519;519)	83	77		
Headache (N=519;518)	176	187		
Fatigue (N=518;518)	183	190		
Rash (N=519;519)	18	15		
Arthralgia (N=518;518)	49	53		
Fever (≥38°C) (N=516;515)	8	7		
Analgesic/antipyretic use (prevention)(N=521;513)	2	3		
Analgesic/antipyretic use (treatment)(N=522;512)	59	69		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any unsolicited AEs

End point title	Number of subjects reporting any unsolicited AEs

End point description:

Safety was assessed as the number of subjects who reported unsolicited AEs following a single injection with either liquid or lyophilized GBS trivalent vaccine formulations.

End point type	Secondary

End point timeframe:

From Day 1 to Day 181 (end of study)

End point values	Liquid GBS trivalent vaccine	Lyophilized GBS trivalent vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	526	521		
Units: Subjects				
Any AEs	272	276		
At least possibly or probably related AEs	57	52		
Medically attended AEs	165	166		
AEs leading to Premature withdrawal	0	0		
AEs leading to Hospitalization	5	9		
AEs leading to Death	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any Serious Adverse Events (SAEs)

End point title	Number of subjects reporting any Serious Adverse Events (SAEs)

End point description:

Safety was assessed as the number of subjects who reported unsolicited SAEs following a single injection with either liquid or lyophilized GBS trivalent vaccine formulations.
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.

End point type	Secondary

End point timeframe:

From Day 1 to Day 181 (end of study)

End point values	Liquid GBS trivalent vaccine	Lyophilized GBS trivalent vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	526	521		
Units: Subjects				
Any SAEs	6	9		
At least possibly or probably related SAEs	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Safety was assessed from day 1 to Day 181 (end of study). The analyses for serious unsolicited adverse events (SAEs) and adverse events (AEs) were done on the safety population.

Adverse event reporting additional description:

Solicited local and systemic AEs were collected daily from day 1 through day 7 after vaccination.
All unsolicited AEs including SAEs were collected from day 1 through day 181 (end of study) after vaccination. There were 3 subjects in the Liquid GBS trivalent vaccine group who were treated but for whom no safety data were available.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Liquid GBS trivalent vaccine

Reporting group description:

Healthy non-pregnant women aged 18-40 years that received a single dose of liquid GBS trivalent vaccine.

Reporting group title	Lyophilized GBS trivalent vaccine

Reporting group description:

Healthy non-pregnant women aged 18-40 years that received a single dose of lyophilized GBS trivalent vaccine.

Serious adverse events	Liquid GBS trivalent vaccine	Lyophilized GBS trivalent vaccine	
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 526 (1.14%)	9 / 521 (1.73%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 526 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Ligament rupture			
subjects affected / exposed	1 / 526 (0.19%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			

subjects affected / exposed	1 / 526 (0.19%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	0 / 526 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Varicose vein			
subjects affected / exposed	0 / 526 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 526 (0.19%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 526 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	0 / 526 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 526 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 526 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	1 / 526 (0.19%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometriosis			
subjects affected / exposed	1 / 526 (0.19%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pneumothorax spontaneous			
subjects affected / exposed	0 / 526 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 526 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	1 / 526 (0.19%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	0 / 526 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 526 (0.19%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			

subjects affected / exposed	0 / 526 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	0 / 526 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Liquid GBS trivalent vaccine	Lyophilized GBS trivalent vaccine	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	439 / 526 (83.46%)	430 / 521 (82.53%)	
Nervous system disorders			
Headache			
subjects affected / exposed	188 / 526 (35.74%)	208 / 521 (39.92%)	
occurrences (all)	188	208	
General disorders and administration site conditions			
Chills			
subjects affected / exposed	67 / 526 (12.74%)	57 / 521 (10.94%)	
occurrences (all)	67	57	
Fatigue			
subjects affected / exposed	186 / 526 (35.36%)	194 / 521 (37.24%)	
occurrences (all)	186	194	
Injection site erythema			
subjects affected / exposed	88 / 526 (16.73%)	84 / 521 (16.12%)	
occurrences (all)	88	84	
Injection site haemorrhage			
subjects affected / exposed	33 / 526 (6.27%)	38 / 521 (7.29%)	
occurrences (all)	33	38	
Injection site induration			
subjects affected / exposed	69 / 526 (13.12%)	60 / 521 (11.52%)	
occurrences (all)	69	60	
Injection site pain			

subjects affected / exposed	238 / 526 (45.25%)	220 / 521 (42.23%)	
occurrences (all)	238	220	
Injection site swelling			
subjects affected / exposed	42 / 526 (7.98%)	32 / 521 (6.14%)	
occurrences (all)	42	32	
Injection site warmth			
subjects affected / exposed	73 / 526 (13.88%)	57 / 521 (10.94%)	
occurrences (all)	73	57	
Malaise			
subjects affected / exposed	105 / 526 (19.96%)	104 / 521 (19.96%)	
occurrences (all)	105	104	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	86 / 526 (16.35%)	81 / 521 (15.55%)	
occurrences (all)	86	81	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	55 / 526 (10.46%)	57 / 521 (10.94%)	
occurrences (all)	55	57	
Myalgia			
subjects affected / exposed	76 / 526 (14.45%)	80 / 521 (15.36%)	
occurrences (all)	76	80	
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	39 / 526 (7.41%)	23 / 521 (4.41%)	
occurrences (all)	39	23	

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