Clinical trial results:
A phase III, single-group, open-label study to assess the safety and reactogenicity of GSK Biologicals' combined reduced-antigen-content diphtheria-tetanus-acellular pertussis (dTpa) vaccine Boostrix administered as a booster vaccine dose in healthy Vietnamese children.

Summary

EudraCT number	2013-003859-37
Trial protocol	Outside EU/EEA
Global end of trial date	10 May 2014

Results information

Result version number	v1
This version publication date	18 April 2016
First version publication date	13 May 2015

Trial information

Trial identification

Sponsor protocol code	115739

Additional study identifiers

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

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	24 July 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 May 2014
Global end of trial reached?	Yes
Global end of trial date	10 May 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and reactogenicity of the study vaccine in terms of solicited symptoms, unsolicited symptoms and serious adverse events (SAEs).

Protection of trial subjects:

All subjects were supervised after vaccination/product administration with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 February 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	Vietnam: 302
Worldwide total number of subjects	302
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	302
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

During the screening the following steps occurred: check for inclusion/exclusion criteria, contraindications/precautions, medical history of the subjects and signing informed consent forms.

Pre-assignment period milestones

Number of subjects started	302
Number of subjects completed	300

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Excluded due to allergic reaction: 2

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

Arm title	Boostrix Group
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Boostrix™
Investigational medicinal product code	
Other name	dTpa
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single-dose administered, on day 0, intramuscularly in the deltoid region of non-dominant arm.

Number of subjects in period 1[1]	Boostrix Group
Started	300
Completed	300

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: Two subjects were excluded from the study due to an allergic reaction.

Baseline characteristics

Reporting groups

Reporting group title	Boostrix Group

Reporting group description: -

Reporting group values	Boostrix Group	Total	
Number of subjects	300	300	
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	7.9		
standard deviation	± 1.38	-	
Gender categorical Units: Subjects			
Female	151	151	
Male	149	149	

End points

End points reporting groups

Reporting group title	Boostrix Group

Reporting group description: -

Primary: Numbers of subjects with any and grade 3 solicited local symptoms

End point title	Numbers of subjects with any and grade 3 solicited local symptoms[1]

End point description:

End point type	Primary

End point timeframe:

Within 4 days (Days 0-3) post vaccination period

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	Boostrix Group			
Subject group type	Reporting group			
Number of subjects analysed	300			
Units: subjects				
Any Pain	105			
Any Redness	55			
Any Swelling	40			
Grade 3 Pain	1			
Grade 3 Redness	1			
Grade 3 Swelling	3			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any, grade 3 and related solicited general symptoms

End point title	Number of subjects with any, grade 3 and related solicited general symptoms[2]

End point description:

End point type	Primary

End point timeframe:

Within 4 days (Days 0-3) post vaccination period

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	Boostrix Group			
Subject group type	Reporting group			
Number of subjects analysed	300			
Units: subjects				
Any Fatigue	42			
Any Gastrointestinal symptoms	15			
Any Headache	33			
Any Temperature	14			
Grade 3 Fatigue	1			
Grade 3 Gastrointestinal symptoms	0			
Grade 3 Headache	0			
Grade 3 Temperature	0			
Related Fatigue	40			
Related Gastrointestinal symptoms	14			
Related Headache	33			
Related Temperature	13			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with unsolicited adverse events (AEs)

End point title	Number of subjects with unsolicited adverse events (AEs)[3]

End point description:

End point type	Primary

End point timeframe:

Within 31 days (Days 0-30) post vaccination period

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	Boostrix Group			
Subject group type	Reporting group			
Number of subjects analysed	300			
Units: subjects				
Any unsolicited AEs	19			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with serious adverse events (SAEs)

End point title	Number of subjects with serious adverse events (SAEs)[4]

End point description:

End point type	Primary

End point timeframe:

During the entire study period

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	Boostrix Group			
Subject group type	Reporting group			
Number of subjects analysed	300			
Units: subjects				
Any SAEs	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms during the 4-day post-vaccination period, Unsolicited AEs during the 31-day post-vaccination period, SAEs during the entire period.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	Boostrix Group

Reporting group description: -

Serious adverse events	Boostrix Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 300 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	Boostrix Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	105 / 300 (35.00%)		
General disorders and administration site conditions			
Pain			
subjects affected / exposed	105 / 300 (35.00%)		
occurrences (all)	105		
Redness			
subjects affected / exposed	55 / 300 (18.33%)		
occurrences (all)	55		
Swelling			
subjects affected / exposed	40 / 300 (13.33%)		
occurrences (all)	40		
Fatigue			

subjects affected / exposed	42 / 300 (14.00%)		
occurrences (all)	42		
Gastrointestinal symptoms			
subjects affected / exposed	15 / 300 (5.00%)		
occurrences (all)	15		
Headache			
subjects affected / exposed	33 / 300 (11.00%)		
occurrences (all)	33		

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