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	v2 (current)
This version publication date	18 May 2018
First version publication date	13 May 2015
Version creation reason	• Correction of full data set Minor corrections of the full study results.

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:

Out of the 302 subjects enrolled into the study, 2 were excluded due to developing allergic reactions and hence only 300 started the study.

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:

Subjects received a single dose of Boostrix vaccine at 6-10 years of age.

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:	
Subjects received a single dose of Boostrix vaccine at 6-10 years of age.	

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	
Race/Ethnicity Units: Subjects			
Asian-South East Asian heritage	300	300	

End points

End points reporting groups

Reporting group title	Boostrix Group

Reporting group description:

Subjects received a single dose of Boostrix vaccine at 6-10 years of age.

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:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 100 millimeters (mm) of injection site. Relationship analysis was not performed.

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:

Assessed solicited general symptoms were fatigue, gastrointestinal symptoms, headache and temperature [defined as axillary temperature equal to or above 37.5 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.0 °C. Related = symptom assessed by the investigator as related to the vaccination.

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:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms.

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:

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	Primary

End point timeframe:

During the entire study period (From Day 0 to Day 30)

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 (Days 0-3) post-vaccination period, Unsolicited AEs during the 31-day (Days 0-30) post-vaccination period, SAEs during the entire study period (from Day 0 to Day 30).	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups	
Reporting group title	Boostrix Group
Reporting group description: Subjects received a single dose of Boostrix vaccine at 6-10 years of age.	

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	133 / 300 (44.33%)		
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