Clinical trial results:
A phase IV, open-label, multi-centre study to assess the long-term persistence of hepatitis A and B antibodies in healthy adult subjects, primed 16 to 20 years earlier with GSK Biologicals' combined hepatitis A and B vaccine, Twinrix (SB208127) in study HAB-084 (208127/084).

Summary

EudraCT number	2013-004586-13
Trial protocol	BE CZ
Global end of trial date	19 November 2014

Results information

Result version number	v1 (current)
This version publication date	22 December 2018
First version publication date	22 December 2018
Summary attachment (see zip file)	Cancelled before Active Statement (2013-004586-13) (Cancelled before Active Statement (2013-004586-13).pdf)

Trial information

Trial identification

Sponsor protocol code	117307

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, B-1330
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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	19 November 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 November 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

•To evaluate the persistence of anti-HBs antibodies in terms of seroprotection rate and geometric mean concentrations (GMCs), 16 to 20 years after the first vaccine dose.
•To evaluate the persistence of anti-HAV antibodies in terms of seropositivity rate and GMCs, 16 to 20 years after the first vaccine dose.

Protection of trial subjects:

The study was cancelled before active (see attached statement). No patient entered the study, therefore no results / data are available.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 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: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants, the study was cancelled before active. No patient entered the study, therefore no results / data are available.

Pre-assignment

Screening details:

Study cancelled before active (see attached statement)

Period 1

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

Arms

Arm title	No-Arm

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Twinrix Adult
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

The product was not administered as the study was cancelled before active.

Number of subjects in period 1	No-Arm
Started	99999
Completed	99999

Baseline characteristics

Reporting groups	
Reporting group title	No-Arm

Reporting group description: -

Reporting group values	No-Arm	Total	
Number of subjects	99999	99999	
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	 0 ± 0	 -	
Gender categorical Units: Subjects			
All	99999	99999	

End points

End points reporting groups

Reporting group title	No-Arm

Reporting group description: -

Primary: No endpoint results

End point title	No endpoint results[1]

End point description:

End point type	Primary

End point timeframe:

The study was cancelled before active (see attached statement)

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 study was cancelled before active (see attached statement).

End point values	No-Arm			
Subject group type	Reporting group			
Number of subjects analysed	99999			
Units: Subjects	99999			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
The study was cancelled before active (see attached statement)	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: The study was cancelled before active (see attached statement).

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? Yes

Date	Interruption	Restart date
19 November 2014	The study was cancelled before active (see attached statement).	-

Notes:

Limitations and caveats

None reported