



Clinical trial results:

An open, randomized, controlled, phase II study to evaluate the safety and immunogenicity of GlaxoSmithKline Biologicals' 11-valent pneumococcal conjugate vaccine, when administered intramuscularly as a 3, 5, 12 month vaccination schedule, as part of a staggered vaccination schedule

Summary

EudraCT number	2004-001823-39
Trial protocol	SE
Global end of trial date	27 November 2012

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 (2004-001823-39 - 103502 - 11PN-PD-DIT-010-Cancelled before Active Statement.pdf)

Trial information

Trial identification

Sponsor protocol code	103502
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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, 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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 November 2012
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	27 November 2012
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the immune response post-dose 2 elicited by GSK Biologicals' candidate 11Pn-PD-DiT vaccine administered according to a 3, 5, 12 month vaccination schedule as part of a staggered vaccination schedule with co-administration of Infanrix™ penta and GSK Biologicals' candidate HibMenC-TT vaccine at 2, 4 months of age.

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	01 November 2004
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	Sweden: 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)	99999
Children (2-11 years)	0
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:

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	GSK Biologicals' 11-valent Pn-PD-DiT vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for 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	0
Not completed	99999
Study was cancelled before active	99999

Baseline characteristics

End points

End points reporting groups

Reporting group title	No-Arm
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Reporting group description: -

Primary: No endpoint results

End point title	No endpoint results ^[1]
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End point description:

End point type	Primary
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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	9999			
Units: Participants	0			

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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	8.0
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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
27 November 2012	The study was cancelled before active (see attached statement).	-

Notes:

Limitations and caveats

None reported