

**Clinical trial results:**

A phase IV, open-label, study to assess the antibody persistence in healthy 5-year-old children, previously vaccinated at 3, 5 and 11 months of age with GSK Biologicals' DTPa-HBV-IPV/Hib or DTPa-IPV/Hib vaccine, in study 105539 (10PN-PD-DIT-002).

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2011-000943-26
Trial protocol	SE NO
Global end of trial date	15 July 2011

Results information

Result version number	v2
This version publication date	08 July 2016
First version publication date	13 February 2015
Version creation reason	<ul style="list-style-type: none">• New data added to full data set• Correction of full data set- Data correction due to a system error in EudraCT – Results- Data for primary endpoints have been added: Number of subjects with anti-HBs antibody concentrations ≥ 6.2 mIU/mL

Trial information**Trial identification**

Sponsor protocol code	115375
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01358825
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, 004 8773793718, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 004 8773793718, 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	09 August 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 July 2011
Global end of trial reached?	Yes
Global end of trial date	15 July 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the immunogenicity of the DTPa-HBV-IPV/Hib and DTPa-IPV/Hib vaccines in terms of persistence of antibodies to all vaccine antigens in 5-year-old children.

Protection of trial subjects:

Since the study does not involve active vaccination, serious adverse events (SAEs) related to study procedures and/or concomitant GSK medication were documented and described in detail.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 May 2011
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	Norway: 46
Country: Number of subjects enrolled	Sweden: 12
Worldwide total number of subjects	58
EEA total number of subjects	58

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)	58
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.

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

Are arms mutually exclusive?	Yes
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Arm title	Infanrix hexa Group
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	Infanrix™ Hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects from Sweden previously vaccinated with 3 doses of Infanrix™ hexa vaccine in the primary study (NCT00307034).

Arm title	Infanrix-IPV/Hib Group
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	Infanrix™ IPV/Hib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects from Norway previously vaccinated with 3 doses of Infanrix™-IPV/Hib vaccine in the primary study (NCT00307034).

Number of subjects in period 1	Infanrix hexa Group	Infanrix-IPV/Hib Group
Started	12	46
Completed	12	45
Not completed	0	1
Blood sample not drawn	-	1

Baseline characteristics

Reporting groups

Reporting group title	Infanrix hexa Group
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Reporting group description: -

Reporting group title	Infanrix-IPV/Hib Group
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Reporting group description: -

Reporting group values	Infanrix hexa Group	Infanrix-IPV/Hib Group	Total
Number of subjects	12	46	58
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	5	5	
standard deviation	± 0	± 0	-
Gender categorical Units: Subjects			
Female	9	14	23
Male	3	32	35

End points

End points reporting groups

Reporting group title	Infanrix hexa Group
Reporting group description: -	
Reporting group title	Infanrix-IPV/Hib Group
Reporting group description: -	

Primary: Number of seroprotected subjects against anti-diphtheria (anti-D) and anti-tetanus (anti-T).

End point title	Number of seroprotected subjects against anti-diphtheria (anti-D) and anti-tetanus (anti-T). ^[1]
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End point description:

A seroprotected subject is a subject with anti-D/anti-T antibody concentrations greater than (\geq) or equal to 0.1 international units per milliliter (IU/mL)

End point type	Primary
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End point timeframe:

At Day 0

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	Infanrix hexa Group	Infanrix-IPV/Hib Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	45		
Units: subjects				
Anti-D [N=12;45]	7	28		
Anti-T [N=12;44]	10	34		

Statistical analyses

No statistical analyses for this end point

Primary: Concentrations of antibodies against anti-D and anti-T

End point title	Concentrations of antibodies against anti-D and anti-T ^[2]
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End point description:

End point type	Primary
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End point timeframe:

At Day 0

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	Infanrix hexa Group	Infanrix-IPV/Hib Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	45		
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D [N=12;45]	0.13 (0.072 to 0.235)	0.196 (0.114 to 0.338)		
Anti-T [N=12;44]	0.29 (0.135 to 0.624)	0.352 (0.207 to 0.599)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN) antibody concentrations ≥ 5 ELISA units per milliliter (EL.U/mL).

End point title	Number of subjects with anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN) antibody concentrations ≥ 5 ELISA units per milliliter (EL.U/mL). ^[3]
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End point description:

End point type	Primary
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End point timeframe:

At Day 0

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	Infanrix hexa Group	Infanrix-IPV/Hib Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	45		
Units: subjects				
Anti-PT	0	9		
Anti-FHA	12	41		
Anti-PRN	8	34		

Statistical analyses

No statistical analyses for this end point

Primary: Concentrations of antibodies against anti-PT, anti-FHA and anti-PRN.

End point title	Concentrations of antibodies against anti-PT, anti-FHA and anti-PRN. ^[4]
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End point description:

End point type	Primary
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End point timeframe:

At Day 0

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	Infanrix hexa Group	Infanrix-IPV/Hib Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	45		
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PT	2.5 (2.5 to 2.5)	4.2 (2.9 to 6)		
Anti-FHA	32.6 (11.5 to 92.5)	50.7 (30.6 to 84.1)		
Anti-PRN	6.2 (3.9 to 9.9)	11.9 (8.4 to 16.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroprotected subjects against anti-hepatitis B surface antigen (anti-HBs).

End point title	Number of seroprotected subjects against anti-hepatitis B surface antigen (anti-HBs). ^{[5][6]}
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End point description:

Seroprotection = anti-HBs antibody concentration \geq 10 milli-international units per milliliter (mIU/mL).

End point type	Primary
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End point timeframe:

At Day 0

Notes:

[5] - 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.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Anti-HBs concentrations assessed only in subjects who previously received a HBs-containing vaccine

End point values	Infanrix hexa Group			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: subjects				
Anti-HBs	5			

Statistical analyses

No statistical analyses for this end point

Primary: Concentrations of antibodies against anti-HBs.

End point title	Concentrations of antibodies against anti-HBs. ^{[7][8]}
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End point description:

End point type	Primary
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End point timeframe:

At Day 0

Notes:

[7] - 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.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Anti-HBs concentrations assessed only in subjects primed with a HBs-containing vaccine

End point values	Infanrix hexa Group			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs	9 (3.9 to 20.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroprotected subjects against anti-polyribosyl ribitol phosphate (anti-PRP).

End point title	Number of seroprotected subjects against anti-polyribosyl ribitol phosphate (anti-PRP). ^[9]
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End point description:

A seroprotected subject is a subject with anti-PRP antibody concentrations ≥ 0.15 micrograms per milliliter ($\mu\text{g/mL}$)

End point type	Primary
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End point timeframe:

At Day 0

Notes:

[9] - 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	Infanrix hexa Group	Infanrix-IPV/Hib Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	45		
Units: subjects				
Anti-PRP	10	40		

Statistical analyses

No statistical analyses for this end point

Primary: Concentrations of antibodies against anti-PRP.

End point title	Concentrations of antibodies against anti-PRP. ^[10]
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End point description:

End point type	Primary
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End point timeframe:

At Day 0

Notes:

[10] - 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	Infanrix hexa Group	Infanrix-IPV/Hib Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	45		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP	0.404 (0.22 to 0.743)	0.886 (0.558 to 1.407)		

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). ^[11]
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End point description:

Assessed SAEs 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
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End point timeframe:

During the entire study period

Notes:

[11] - 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	Infanrix hexa Group	Infanrix-IPV/Hib Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	46		
Units: subjects				
SAEs	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with anti-HBs antibody concentrations ≥ 6.2 mIU/mL

End point title	Number of subjects with anti-HBs antibody concentrations ≥ 6.2 mIU/mL ^{[12][13]}
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End point description:

End point type	Primary
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End point timeframe:

At Day 0

Notes:

[12] - 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.

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Anti-HBs concentrations assessed only in subjects primed with a HBs-containing vaccine

End point values	Infanrix hexa Group			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Subjects				
Anti-HBs	6			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

SAEs: during the entire study period

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	14
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Reporting groups

Reporting group title	Infanrix-IPV/Hib Group
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Reporting group description: -

Reporting group title	Infanrix hexa Group
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Reporting group description: -

Serious adverse events	Infanrix-IPV/Hib Group	Infanrix hexa Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 46 (0.00%)	0 / 12 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	Infanrix-IPV/Hib Group	Infanrix hexa Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 46 (0.00%)	0 / 12 (0.00%)	

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: Adverse events were not collected as the study did not involve any vaccination.

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