



## Clinical trial results:

**An open, phase IV, single-group multicentre study to assess the long-term persistence of antibodies against hepatitis B and the immune response to a hepatitis B vaccine challenge in children at 4-5 years of age, previously primed and boosted in the first two years of life with GlaxoSmithKline (GSK) Biologicals' DTPa-HBV-IPV/Hib vaccine.**

### Summary

EudraCT number	2006-000556-41
Trial protocol	DE
Global end of trial date	14 May 2007

### Results information

Result version number	v2 (current)
This version publication date	31 July 2016
First version publication date	06 June 2015
Version creation reason	• Correction of full data set Data (typos) were corrected.

### Trial information

#### Trial identification

Sponsor protocol code	106789
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00411697
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:

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**Results analysis stage**

Analysis stage	Final
Date of interim/final analysis	11 January 2008
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 May 2007
Global end of trial reached?	Yes
Global end of trial date	14 May 2007
Was the trial ended prematurely?	No

Notes:

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**General information about the trial**

Main objective of the trial:

To assess the anti-HBs antibody response to a challenge dose of HBV vaccine in subjects at 4-5 years of age, previously vaccinated with 4 doses of DTPa-HBV-IPV/Hib vaccine in the first 2 years of life.

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	19 December 2006
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

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**Population of trial subjects****Subjects enrolled per country**

Country: Number of subjects enrolled	Germany: 301
Worldwide total number of subjects	301
EEA total number of subjects	301

Notes:

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**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)	301
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

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

Dosage and administration details:

Subjects received a single dose of hepatitis B vaccine injected intramuscularly into the deltoid region of the left arm.

Number of subjects in period 1	Engerix-B Kinder Group
Started	301
Completed	300
Not completed	1
Consent withdrawn by subject	1

## Baseline characteristics

### Reporting groups

Reporting group title	Engerix-B Kinder Group
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Reporting group description: -

Reporting group values	Engerix-B Kinder Group	Total	
Number of subjects	301	301	
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	4.5		
standard deviation	± 0.52	-	
Gender categorical Units: Subjects			
Female	153	153	
Male	148	148	

## End points

### End points reporting groups

Reporting group title	Engerix-B Kinder Group
Reporting group description: -	

### Primary: Number of subjects with anti-hepatitis B surface antigen (anti-HBs) antibody concentrations $\geq 100$ mIU/mL

End point title	Number of subjects with anti-hepatitis B surface antigen (anti-HBs) antibody concentrations $\geq 100$ mIU/mL <sup>[1]</sup>
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End point description:

End point type	Primary
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End point timeframe:

1 Month post vaccination

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	Engerix-B Kinder Group			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Subjects				
Anti-HBs, Post	274			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with anti-HBs antibody concentrations $\geq 10$ mIU/mL

End point title	Number of subjects with anti-HBs antibody concentrations $\geq 10$ mIU/mL
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End point description:

End point type	Secondary
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End point timeframe:

1 Month post vaccination

<b>End point values</b>	Engerix-B Kinder Group			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Subjects				
Anti-HBs, Post	281			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Anti-HBs antibody concentrations

End point title	Anti-HBs antibody concentrations
End point description:	
End point type	Secondary
End point timeframe:	
1 Month post vaccination	

<b>End point values</b>	Engerix-B Kinder Group			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs, Post	8711.8 (6620.3 to 11464.1)			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with anti-HBs antibody concentrations $\geq 10$ mIU/mL

End point title	Number of subjects with anti-HBs antibody concentrations $\geq 10$ mIU/mL
End point description:	
End point type	Secondary
End point timeframe:	
Before vaccination	

<b>End point values</b>	Engerix-B Kinder Group			
Subject group type	Reporting group			
Number of subjects analysed	293			
Units: Subjects				
Anti-HBs, Pre	250			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with anti-HBs antibody concentrations $\geq 10$ mIU/mL and $< 100$ mIU/mL

End point title	Number of subjects with anti-HBs antibody concentrations $\geq 10$ mIU/mL and $< 100$ mIU/mL
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End point description:

End point type	Secondary
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End point timeframe:

Before vaccination

<b>End point values</b>	Engerix-B Kinder Group			
Subject group type	Reporting group			
Number of subjects analysed	293			
Units: Subjects				
Anti-HBs, Pre	114			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with anti-HBs antibody concentrations $\geq 100$ mIU/mL

End point title	Number of subjects with anti-HBs antibody concentrations $\geq 100$ mIU/mL
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End point description:

End point type	Secondary
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End point timeframe:

Before vaccination

<b>End point values</b>	Engerix-B Kinder Group			
Subject group type	Reporting group			
Number of subjects analysed	293			
Units: Subjects				
Anti-HBs, Pre	136			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Anti-HBs antibody concentrations

End point title	Anti-HBs antibody concentrations
End point description:	
End point type	Secondary
End point timeframe:	
Before vaccination	

<b>End point values</b>	Engerix-B Kinder Group			
Subject group type	Reporting group			
Number of subjects analysed	293			
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs, Pre	87.8 (71.5 to 107.9)			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with unsolicited adverse events (AEs)

End point title	Number of subjects with unsolicited adverse events (AEs)
End point description:	
End point type	Secondary
End point timeframe:	
Within Day 0-30 following vaccination	



<b>End point values</b>	Engerix-B Kinder Group			
Subject group type	Reporting group			
Number of subjects analysed	301			
Units: Subjects				
AEs	15			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with serious adverse events (SAEs)

End point title	Number of subjects with serious adverse events (SAEs)
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End point description:

End point type	Secondary
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End point timeframe:

During the entire study period

<b>End point values</b>	Engerix-B Kinder Group			
Subject group type	Reporting group			
Number of subjects analysed	301			
Units: Subjects				
SAEs	0			

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

SAEs during the entire study period. Unsolicited adverse events day 0-30 following vaccination.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	9.1
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### Reporting groups

Reporting group title	Engerix-B Kinder Group
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Reporting group description: -

<b>Serious adverse events</b>	Engerix-B Kinder Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 301 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

<b>Non-serious adverse events</b>	Engerix-B Kinder Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 301 (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: Reported non-serious adverse events are under the 5% frequency threshold.

## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported