Clinical trial results:
Antibody persistence in 11 to 13-year-old children previously vaccinated at 6 years old with either REVAXIS® or DT Polio®, and immune response to a booster dose of TETRAVAC-ACELLULAIRE®

Summary

EudraCT number	2011-004458-25
Trial protocol	FR
Global end of trial date	17 December 2012

Results information

Result version number	v1 (current)
This version publication date	27 April 2016
First version publication date	03 June 2015

Trial information

Trial identification

Sponsor protocol code	RVX01C

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01546909
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur MSD S.N.C.
Sponsor organisation address	162 avenue Jean Jaurès - CS 50712, Lyon Cedex 07, France, 69367
Public contact	Clinical Trials Disclosure, Sanofi Pasteur MSD, ClinicalTrialsDisclosure@spmsd.com
Scientific contact	Clinical Trials Disclosure, Sanofi Pasteur MSD, ClinicalTrialsDisclosure@spmsd.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	17 December 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 December 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe in 11 to 13-year-old children who received 1 dose of either REVAXIS® or DT Polio® at 6 years of age the antibody persistence in terms of proportions of subjects with antibody concentrations ≥0.01 IU/mL against diphtheria and tetanus, and antibody titres ≥8 (1/dilution) against poliovirus types 1, 2 & 3.
To describe 1 month after a booster dose of TETRAVAC-ACELLULAIRE® when given to 11 to 13-year-old children who received 1 dose of either REVAXIS® or DT Polio® at 6 years of age the immune responses in terms of proportions of subjects with antibody concentrations ≥0.1 IU/mL against diphtheria and tetanus, and antibody titres ≥8 (1/dilution) against poliovirus types 1, 2 & 3.

Protection of trial subjects:

Children in the study received a single booster dose of TETRAVAC-ACELLULAIRE supplied in a pre-filled 0.5 mL syringe. Children with known true hypersensitity to at least 1 of the components of the vaccine components were not vaccinated.
The sheduled administration was in accordance with the European Summary of Product Characteristics and French recommendations.
Vaccine was administered by qualified study personnel. After each vaccination, children were kept under observation for 20 minutes.

Background therapy:

The present study was a 5-year follow-up of study F05-TdI-301.
Children (11 to 13 years of age) were therefore vaccinated with either REVAXIS (diphtheria, tetanus and polio 1, 2 & 3 (inactivated) vaccine (adsorbed, reduced antigen(s) content)) or DT Polio (diphtheria, tetanus and polio 1, 2 & 3 (inactivated) vaccine) at 6 years of age.

Evidence for comparator:

Children received 1 dose of TETRAVAC-ACELLULAIRE. No comparator product was thus used during study RVX01C. However, children were previously vaccinated with either REVAXIS or DT Polio at 6 years of age in study F05-TdI-301. There were thus 2 groups of subjects in the present study: REVAXIS group and DT Polio group.

Actual start date of recruitment	22 February 2012
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	France: 274
Worldwide total number of subjects	274
EEA total number of subjects	274

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)	270
Adolescents (12-17 years)	4
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The present study was a follow-up of study F05-TdI-301. Study participants were recruited among the participants of the F05-TdI-301 study between 22 February 2012 and 30 June 2012 in 44 active centres in France.

Pre-assignment

Screening details:

277 subjects were screened out.
274 subjects who met all the inclusion criteria but none of the exclusion criteria were included.
272 subjects had blood serological results for blood sample 1 (i.e., before TETRAVAC-ACELLULAIRE administration).
274 subjects were vaccinated with TETRAVAC-ACELLULAIRE.

Period 1

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

Blinding implementation details:

This is not applicable, as this study was an open-label study and all subjects received the same vaccine, TETRAVAC-ACELLULAIRE. Serology tests were performed by laboratory staffs that were blinded to which group each subject was allocated to (previous vaccination with REVAXIS or DT Polio at 6 years of age).

Arms

Are arms mutually exclusive?	Yes
Arm title	REVAXIS Group

Arm description:

Participants received a single dose of booster TETRAVAC-ACELLULAIRE approximately 5 years after vaccination with 1 dose of REVAXIS (diphtheria, tetanus and poliovirus (inactivated) vaccine (adsorbed, reduced antigen(s) content)), given at 6 years of age.

Arm type	Experimental
Investigational medicinal product name	TETRAVAC-ACELLULAIRE®
Investigational medicinal product code	DTaP-IPV
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5 mL dose (intramuscular, deltoid) at 11-13 years of age.

Arm title	DT Polio Group

Arm description:

Participants received a single dose of booster TETRAVAC-ACELLULAIRE approximately 5 years after vaccination with 1 dose of DT Polio (diphtheria, tetanus and inactivated poliovirus vaccine), given at 6 years of age.

Arm type	Active comparator
Investigational medicinal product name	TETRAVAC-ACELLULAIRE®
Investigational medicinal product code	DTaP-IPV
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5 mL dose (intramuscular, deltoid) at 11-13 years of age.

Number of subjects in period 1	REVAXIS Group	DT Polio Group
Started	129	145
Completed	128	142
Not completed	1	3
Consent withdrawn by subject	1	2
Lost to follow-up	-	1

Baseline characteristics

Reporting groups	
Reporting group title	REVAXIS Group
Reporting group description:	
Participants received a single dose of booster TETRAVAC-ACELLULAIRE approximately 5 years after vaccination with 1 dose of REVAXIS (diphtheria, tetanus and poliovirus (inactivated) vaccine (adsorbed, reduced antigen(s) content)), given at 6 years of age.	
Reporting group title	DT Polio Group
Reporting group description:	
Participants received a single dose of booster TETRAVAC-ACELLULAIRE approximately 5 years after vaccination with 1 dose of DT Polio (diphtheria, tetanus and inactivated poliovirus vaccine), given at 6 years of age.	

Reporting group values	REVAXIS Group	DT Polio Group	Total
Number of subjects	129	145	274
Age categorical			
Units: Subjects			
Children (2-11 years)	128	142	270
Adolescents (12-17 years)	1	3	4
Age continuous			
Units: years			
arithmetic mean	11.4	11.3	
standard deviation	± 0.3	± 0.3	-
Gender categorical			
Units: Subjects			
Female	61	77	138
Male	68	68	136
Weight continuous			
Units: kg			
arithmetic mean	40.2	41.4	
standard deviation	± 8.8	± 10.1	-
Height continuous			
Units: cm			
arithmetic mean	147.3	148.3	
standard deviation	± 7.1	± 7.7	-

End points

End points reporting groups

Reporting group title	REVAXIS Group
Reporting group description:	
Participants received a single dose of booster TETRAVAC-ACELLULAIRE approximately 5 years after vaccination with 1 dose of REVAXIS (diphtheria, tetanus and poliovirus (inactivated) vaccine (adsorbed, reduced antigen(s) content)), given at 6 years of age.	
Reporting group title	DT Polio Group
Reporting group description:	
Participants received a single dose of booster TETRAVAC-ACELLULAIRE approximately 5 years after vaccination with 1 dose of DT Polio (diphtheria, tetanus and inactivated poliovirus vaccine), given at 6 years of age.	

Primary: Antibody persistence # Proportion of subjects with anti-diphtheria and anti-tetanus concentrations ≥0.01 IU/mL and anti-polio 1, 2 & 3 titres ≥8 (1/dil) approximately 5 years after vaccination with either REVAXIS or DT Polio at 6 years of age

End point title	Antibody persistence # Proportion of subjects with anti-diphtheria and anti-tetanus concentrations ≥0.01 IU/mL and anti-polio 1, 2 & 3 titres ≥8 (1/dil) approximately 5 years after vaccination with either REVAXIS or DT Polio at 6 years of age[1]
End point description:	
Percentage of subjects with an anti-diphtheria concentration ≥0.01 IU/mL (measured by seroneutralisation (SN)), an anti-tetanus concentration ≥0.01 IU/mL (measured by Enzyme-Linked ImmunoSorbent Assay (ELISA)), and anti-poliomyelitis types 1, 2 & 3 (IPV1, 2 & 3) titres ≥8 (1/dilution (1/dil)) (measured by SN), approximately 5 years after vaccination with 1 dose of either REVAXIS or DT Polio. Analysis was done on the Antibody Persistence Full Analysis set (i.e., all subjects with pre-vaccination immunogenicity evaluation, N= 272). Note: (N=***, ***) represents the number of assessed subjects in the REVAXIS and DT Polio groups, respectively.	
End point type	Primary
End point timeframe:	
Approximately 5 years after vaccination with 1 dose of either REVAXIS or DT Polio, given at 6 years of age.	
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: No hypothesis was defined as this study was only descriptive.	

End point values	REVAXIS Group	DT Polio Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	128	144		
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-diphtheria ≥0.01 IU/mL (SN) (N= 128, 144)	98.4 (94.5 to 99.8)	99.3 (96.2 to 100)		
Anti-tetanus ≥0.01 IU/mL (ELISA) (N= 128, 144)	100 (97.2 to 100)	100 (97.5 to 100)		
Anti-IPV1 ≥8 (1/dil) (SN) (N= 128, 144)	98.4 (94.5 to 99.8)	100 (97.5 to 100)		
Anti-IPV2 ≥8 (1/dil) (SN) (N= 128, 144)	100 (97.2 to 100)	100 (97.5 to 100)		

Anti-IPV3 ≥8 (1/dil) (SN) (N= 128, 144)	99.2 (95.7 to 100)	96.5 (92.1 to 98.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Post-booster immune response # Proportion of subjects with anti-diphtheria and anti-tetanus concentrations ≥0.1 IU/mL and anti-polio 1, 2 & 3 titres ≥8 (1/dil) 1 month after a booster dose of TETRAVAC-ACELLULAIRE

End point title	Post-booster immune response # Proportion of subjects with anti-diphtheria and anti-tetanus concentrations ≥0.1 IU/mL and anti-polio 1, 2 & 3 titres ≥8 (1/dil) 1 month after a booster dose of TETRAVAC-ACELLULAIRE[2]

End point description:

Percentage of subjects with an anti-diphtheria concentration ≥0.1 IU/mL (measured by seroneutralisation (SN)), an anti-tetanus concentration ≥0.1 IU/mL (measured by Enzyme-Linked ImmunoSorbent Assay (ELISA)), and anti-poliomyelitis types 1, 2 & 3 (IPV1, 2 & 3) titres ≥8 (1/dilution (1/dil)) (measured by SN), 1 month after a booster dose of TETRAVAC-ACELLULAIRE in 11-13 years of age children who received 1 dose of either REVAXIS or DT Polio at 6 years of age.
Analysis was done on the Post-Booster Per Protocol set (i.e., all included subjects excluding subjects with protocol violation which may interfere with the immunogenicity evaluation of the study vaccine, N= 255).

Note: (N=***, ***) represents the number of assessed subjects in the REVAXIS and DT Polio groups, respectively.

End point type	Primary

End point timeframe:

One month after a booster dose of TETRAVAC-ACELLULAIRE, given approximately 5 years after 1 dose of either REVAXIS or DT Polio.

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: No hypothesis was defined as this study was only descriptive.

End point values	REVAXIS Group	DT Polio Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	124	131		
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-diphtheria ≥0.1 IU/mL (SN) (N= 124, 131)	100 (97.1 to 100)	100 (97.2 to 100)		
Anti-tetanus ≥0.1 IU/mL (ELISA) (N= 124, 131)	100 (97.1 to 100)	100 (97.2 to 100)		
Anti-IPV1 ≥8 (1/dil) (SN) (N= 124, 131)	100 (97.1 to 100)	100 (97.2 to 100)		
Anti-IPV2 ≥8 (1/dil) (SN) (N= 124, 131)	100 (97.1 to 100)	100 (97.2 to 100)		
Anti-IPV3 ≥8 (1/dil) (SN) (N= 124, 131)	100 (97.1 to 100)	100 (97.2 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody persistence # Proportion of subjects with anti-diphtheria and anti-tetanus concentrations ≥0.1 IU/mL approximately 5 years after vaccination with either REVAXIS or DT Polio at 6 years of age

End point title	Antibody persistence # Proportion of subjects with anti-diphtheria and anti-tetanus concentrations ≥0.1 IU/mL approximately 5 years after vaccination with either REVAXIS or DT Polio at 6 years of age

End point description:

Percentage of subjects with an anti-diphtheria concentration ≥0.1 IU/mL (measured by seroneutralisation (SN) and Enzyme-Linked ImmunoSorbent Assay (ELISA)), and an anti-tetanus concentration ≥0.1 IU/mL (measured by ELISA), approximately 5 years after vaccination with 1 dose of either REVAXIS or DT Polio, given at 6 years of age.
Analysis was done on the Antibody Persistence Full Analysis set (i.e., all subjects with pre-vaccination immunogenicity evaluation, N= 272).

Note: (N=***, ***) represents the number of assessed subjects in the REVAXIS and DT Polio groups, respectively.

End point type	Secondary

End point timeframe:

Approximately 5 years after vaccination with 1 dose of either REVAXIS or DT Polio, given at 6 years of age.

End point values	REVAXIS Group	DT Polio Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	128	144		
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-diphtheria ≥0.1 IU/mL (SN) (N= 128, 144)	63.3 (54.3 to 71.6)	86.1 (79.4 to 91.3)		
Anti-diphtheria ≥0.1 IU/mL (ELISA) (N= 128, 144)	67.2 (58.3 to 75.2)	89.6 (83.4 to 94.1)		
Anti-tetanus ≥0.1 IU/mL (ELISA) (N= 128, 144)	96.1 (91.1 to 98.7)	94.4 (89.3 to 97.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody persistence # Geometric Mean Concentrations (GMCs) or Titres (GMTs) of anti-diphtheria, anti-tetanus, and anti-polio 1, 2 & 3 antibodies approximately 5 years after vaccination with either REVAXIS or DT Polio at 6 years of age

End point title	Antibody persistence # Geometric Mean Concentrations (GMCs) or Titres (GMTs) of anti-diphtheria, anti-tetanus, and anti-polio 1, 2 & 3 antibodies approximately 5 years after vaccination with either REVAXIS or DT Polio at 6 years of age

End point description:

Antibody concentrations (diphtheria and tetanus) or titres (poliovirus types 1, 2 & 3) were measured for

diphtheria by seroneutralisation (SN) and Enzyme-Linked ImmunoSorbent Assay (ELISA), for tetanus by ELISA, and for poliomyelitis types 1, 2 & 3 (IPV1, 2 & 3) by SN, approximately 5 years after vaccination with 1 dose of either REVAXIS or DT Polio, given at 6 years of age.
Analysis was done on the Antibody Persistence Full Analysis set (i.e., all subjects with pre-vaccination immunogenicity evaluation, N= 272).

Note: (N=***, ***) represents the number of assessed subjects in the REVAXIS and DT Polio groups, respectively.

End point type	Secondary

End point timeframe:

Approximately 5 years after vaccination with 1 dose of either REVAXIS or DT Polio, given at 6 years of age.

End point values	REVAXIS Group	DT Polio Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	128	144		
Units: Concentrations or Titres				
geometric mean (confidence interval 95%)				
Anti-diphtheria GMC (SN) (N= 128, 144)	0.24 (0.18 to 0.33)	0.62 (0.48 to 0.81)		
Anti-diphtheria GMC (ELISA) (N= 128,144)	0.22 (0.17 to 0.28)	0.46 (0.37 to 0.58)		
Anti-tetanus GMC (ELISA) (N= 128, 143)	0.73 (0.61 to 0.88)	0.91 (0.76 to 1.09)		
Anti-IPV1 GMT (SN) (N= 128, 144)	233 (186 to 291)	259 (216 to 311)		
Anti-IPV2 GMT (SN) (N= 128, 144)	405 (338 to 484)	276 (231 to 331)		
Anti-IPV3 GMT (SN) (N= 128, 144)	314 (255 to 388)	134 (108 to 166)		

Statistical analyses

No statistical analyses for this end point

Secondary: Post-booster immune response # Proportion of subjects with anti-diphtheria concentration ≥0.1 IU/mL, and anti-diphtheria and anti-tetanus concentrations ≥1.0 IU/mL 1 month after a booster dose of TETRAVAC-ACELLULAIRE

End point title	Post-booster immune response # Proportion of subjects with anti-diphtheria concentration ≥0.1 IU/mL, and anti-diphtheria and anti-tetanus concentrations ≥1.0 IU/mL 1 month after a booster dose of TETRAVAC-ACELLULAIRE

End point description:

Percentage of subjects with an anti-diphtheria concentration ≥0.1 IU/mL (measured by Enzyme-Linked ImmunoSorbent Assay (ELISA)), an anti-diphtheria concentration ≥1.0 IU/mL (measured by Seroneutralisation (SN) and ELISA), and an anti-tetanus concentration ≥1.0 IU/mL (measured by ELISA), 1 month after a booster dose of TETRAVAC-ACELLULAIRE in 11-13 years of age children who received 1 dose of either REVAXIS or DT Polio at 6 years of age.
Analysis was done on the Post-Booster Per Protocol set (i.e., all included subjects excluding subjects with protocol violation which may interfere with the immunogenicity evaluation of the study vaccine, N= 255).

Note: (N=***, ***) represents the number of assessed subjects in the REVAXIS and DT Polio groups, respectively.

End point type	Secondary

End point timeframe:

One month after a booster dose of TETRAVAC-ACELLULAIRE, given approximately 5 years after 1 dose of either REVAXIS or DT Polio.

End point values	REVAXIS Group	DT Polio Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	124	131		
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-diphtheria ≥0.1 IU/mL (ELISA) (N= 124, 131)	100 (97.1 to 100)	100 (97.2 to 100)		
Anti-diphtheria ≥1.0 IU/mL (SN) (N= 124, 131)	98.4 (94.3 to 99.8)	96.9 (92.4 to 99.2)		
Anti-diphtheria ≥1.0 IU/mL (ELISA) (N= 124, 131)	99.2 (95.6 to 100)	95.4 (90.3 to 98.3)		
Anti-tetanus ≥1.0 IU/mL (ELISA) (N= 124, 131)	100 (97.1 to 100)	99.2 (95.8 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Post-booster immune response # Geometric Mean Concentrations (GMCs) or Titres (GMTs) of anti-diphtheria, anti-tetanus, and anti-polio 1, 2 & 3 antibodies 1 month after a booster dose of TETRAVAC-ACELLULAIRE

End point title	Post-booster immune response # Geometric Mean Concentrations (GMCs) or Titres (GMTs) of anti-diphtheria, anti-tetanus, and anti-polio 1, 2 & 3 antibodies 1 month after a booster dose of TETRAVAC-ACELLULAIRE

End point description:

Antibody concentrations (diphtheria and tetanus) or titres (poliovirus types 1, 2 & 3) were measured for diphtheria by Seroneutralisation (SN) and Enzyme-Linked ImmunoSorbent Assay (ELISA), for tetanus by ELISA, and for poliomyelitis types 1, 2 & 3 (IPV1,2 & I) by SN, 1 month after a booster dose of TETRAVAC-ACELLULAIRE in 11-13 years of age children who received 1 dose of either REVAXIS or DT Polio at 6 years of age.
Analysis was done on the Post-Booster Per Protocol set (i.e., all included subjects excluding subjects with protocol violation which may interfere with the immunogenicity evaluation of the study vaccine, N= 255).

Note: (N=***, ***) represents the number of assessed subjects in the REVAXIS and DT Polio groups, respectively.

End point type	Secondary

End point timeframe:

One month after a booster dose of TETRAVAC-ACELLULAIRE, given approximately 5 years after 1 dose of either REVAXIS or DT Polio.

End point values	REVAXIS Group	DT Polio Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	124	131		
Units: Concentrations or Titres				
geometric mean (confidence interval 95%)				
Anti-diphtheria GMC (SN) (N= 124, 131)	7.36 (6.08 to 8.92)	7.57 (6.25 to 9.17)		
Anti-diphtheria GMC (ELISA) (N= 124, 131)	5.07 (4.36 to 5.91)	5.45 (4.68 to 6.34)		
Anti-tetanus GMC (ELISA) (N= 124, 131)	8.08 (7.16 to 9.11)	7.83 (6.96 to 8.8)		
Anti-IPV1 GMT (SN) (N= 124, 131)	1557 (1245 to 1948)	1483 (1236 to 1779)		
Anti-IPV2 GMT (SN) (N= 124, 131)	2491 (2028 to 3058)	2432 (2051 to 2884)		
Anti-IPV3 GMT (SN) (N= 124, 131)	1948 (1607 to 2360)	2356 (1924 to 2885)		

Statistical analyses

No statistical analyses for this end point

Secondary: Post-booster immune response # Geometric Mean of individual post/pre-booster Concentration (GMC) or Titre (GMT) Ratios of anti-diphtheria, anti-tetanus, and anti-polio 1, 2 & 3 antibodies 1 month after a booster dose of TETRAVAC-ACELLULAIRE

End point title	Post-booster immune response # Geometric Mean of individual post/pre-booster Concentration (GMC) or Titre (GMT) Ratios of anti-diphtheria, anti-tetanus, and anti-polio 1, 2 & 3 antibodies 1 month after a booster dose of TETRAVAC-ACELLULAIRE

End point description:

Study participants were blood sampled between Day -7 (D-7) and D0 before receiving 1 dose of TETRAVAC-ACELLULAIRE. One month later (D28 to D35, i.e., post-vaccination), study participants were blood sampled again.
Antibody concentrations (diphtheria and tetanus) or titres (poliovirus types 1, 2 & 3) were measured for diphtheria by Seroneutralisation (SN) and Enzyme-Linked ImmunoSorbent Assay (ELISA), for tetanus by ELISA, and for poliomyelitis types 1, 2 & 3 (IPV1, 2 & 3) by SN.
Individual post- (D28-D35) / pre-booster (D0) antibody concentrations or titres ratios were measured for diphtheria, tetanus and poliomyelitis types 1, 2 & 3.
Analysis was done on the Post-Booster Per Protocol set (i.e., all included subjects excluding subjects with protocol violation which may interfere with the immunogenicity evaluation of the study vaccine, N= 255).

Note: (N=***, ***) represents the number of assessed subjects in the REVAXIS and DT Polio groups, respectively.

End point type	Secondary

End point timeframe:

One month after a booster dose of TETRAVAC-ACELLULAIRE, given approximately 5 years after 1 dose of either REVAXIS or DT Polio.

End point values	REVAXIS Group	DT Polio Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	124	131		
Units: Not applicable				
geometric mean (confidence interval 95%)				
Anti-diphtheria GMCR (SN) (N= 123, 130)	32.2 (24.2 to 42.8)	11.6 (9.1 to 14.6)		
Anti-diphtheria GMCR (ELISA) (N= 123, 130)	24.6 (19.4 to 31)	11.7 (9.5 to 14.3)		
Anti-tetanus GMCR (ELISA) (N= 123, 129)	11.5 (9.3 to 14.3)	8.2 (6.8 to 10)		
Anti-IPV1 GMTR (SN) (N= 123, 130)	6.9 (5.2 to 9.2)	5.9 (4.5 to 7.7)		
Anti-IPV2 GMTR (SN) (N= 123, 130)	6.4 (4.9 to 8.3)	8.7 (6.8 to 11.1)		
Anti-IPV3 GMTR (SN) (N= 123, 130)	6.5 (5.1 to 8.4)	17.2 (13.1 to 22.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of subjects reporting solicited injection-site reactions from D0 to D7 after 1 booster dose of TETRAVAC-ACELLULAIRE

End point title	Proportion of subjects reporting solicited injection-site reactions from D0 to D7 after 1 booster dose of TETRAVAC-ACELLULAIRE

End point description:

The subject's parent(s)/legal representative recorded all adverse events (AEs) on the diary card. Solicited Injection-Site Reactions (ISRs) (injection-site erythema, injection-site pain and injection-site swelling) were collected from Day 0 to Day 7 following vaccination with TETRAVAC-ACELLULAIRE.
AEs at injection sites were always considered as related to vaccine (Injection-Site Reactions (ISRs)).
Analysis was done on the Safety set (i.e., all subjects who received the study vaccine and who have safety follow-up data, N= 272).

End point type	Secondary

End point timeframe:

From D0 to D7 following vaccination with 1 booster dose of TETRAVAC-ACELLULAIRE, received approximately 5 years after 1 dose of either REVAXIS or DT Polio.

End point values	REVAXIS Group	DT Polio Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	129	143		
Units: Percentage of subjects				
number (not applicable)				
At least 1 ISR	86.8	88.1		
Injection site erythema	55	39.2		
Injection site pain	85.3	87.4		
Injection site swelling	45.7	37.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of subjects reporting solicited systemic reactions from D0 to D7 after 1 booster dose of TETRAVAC-ACELLULAIRE

End point title	Proportion of subjects reporting solicited systemic reactions from D0 to D7 after 1 booster dose of TETRAVAC-ACELLULAIRE

End point description:

The subject's parent(s)/legal representative recorded all adverse events (AEs) on the diary card.
Solicited systemic reactions (headache, malaise, myalgia and pyrexia) were collected from Day 0 to Day 7 following vaccination with TETRAVAC-ACELLULAIRE.
Pyrexia was defined in this study as a temperature of 38.0°C or over. The highest temperature was recorded in the diary card.
All of these solicited systemic reactions (headache, malaise, myalgia and pyrexia) were assessed as vaccine-related by the investigator.
Analysis was done on the Safety set (i.e., all subjects who received the study vaccine and who have safety follow-up data, N= 272).

End point type	Secondary

End point timeframe:

From D0 to D7 following vaccination with 1 booster dose of TETRAVAC-ACELLULAIRE, received approximately 5 years after 1 dose of either REVAXIS or DT Polio.

End point values	REVAXIS Group	DT Polio Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	129	143		
Units: Percentage of subjects				
number (not applicable)				
At least 1 solicited systemic reaction	46.5	37.1		
Headache	25.6	18.2		
Malaise	8.5	4.2		
Myalgia	35.7	28		
Pyrexia	7	2.1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Unsolicited adverse events were collected in the diary card from D0 to D28 after vaccination with TETRAVAC-ACELLULAIRE, in subjects previously vaccinated with either REVAXIS or DT Polio at 6 years of age (i.e. approximately 5 years before).

Adverse event reporting additional description:

Pyrexia was defined in this study as a temperature of 38.0°C or over.
Analysis of adverse events was done on the Safety set (i.e., all subjects who received the study vaccine and who have safety follow-up data, N= 272).

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups

Reporting group title	REVAXIS Group

Reporting group description:

Participants received a single dose of booster TETRAVAC-ACELLULAIRE approximately 5 years after vaccination with 1 dose of REVAXIS (diphtheria, tetanus and poliovirus (inactivated) vaccine (adsorbed, reduced antigen(s) content)), given at 6 years of age.
The number of subjects reporting at least 1 unsolicited non-serious ISR or AE with incidence ≥1% are presented hereafter. If each unsolicited ISR or AE with incidence ≥1% was reported by a different subject, the number of subjects reporting at least 1 unsolicited ISR or AE with incidence ≥1% would have been 19.

Reporting group title	DT Polio Group

Reporting group description:

Participants received a single dose of booster TETRAVAC-ACELLULAIRE approximately 5 years after vaccination with 1 dose of DT Polio (diphtheria, tetanus and inactivated poliovirus vaccine), given at 6 years of age.
The number of subjects reporting at least 1 unsolicited non-serious ISR or AE with incidence ≥1% are presented hereafter. If each unsolicited ISR or AE with incidence ≥1% was reported by a different subject, the number of subjects reporting at least 1 unsolicited ISR or AE with incidence ≥1% would have been 19.

Serious adverse events	REVAXIS Group	DT Polio Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 129 (0.00%)	0 / 143 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	REVAXIS Group	DT Polio Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 129 (14.73%)	19 / 143 (13.29%)	
Nervous system disorders			
D0-D28, Headache			
subjects affected / exposed	3 / 129 (2.33%)	4 / 143 (2.80%)	
occurrences (all)	3	4	
General disorders and administration site conditions			
D0-D28, Pyrexia			
subjects affected / exposed	1 / 129 (0.78%)	4 / 143 (2.80%)	
occurrences (all)	1	4	
D0-D28, Pruritus			
subjects affected / exposed	3 / 129 (2.33%)	1 / 143 (0.70%)	
occurrences (all)	3	1	
Gastrointestinal disorders			
D0-D28, Nausea			
subjects affected / exposed	2 / 129 (1.55%)	1 / 143 (0.70%)	
occurrences (all)	2	1	
D0-D28, Diarrhoea			
subjects affected / exposed	2 / 129 (1.55%)	0 / 143 (0.00%)	
occurrences (all)	2	0	
Respiratory, thoracic and mediastinal disorders			
D0-D28, Oropharyngeal pain			
subjects affected / exposed	1 / 129 (0.78%)	3 / 143 (2.10%)	
occurrences (all)	1	3	
Musculoskeletal and connective tissue disorders			
D0-D28, Myalgia			
subjects affected / exposed	1 / 129 (0.78%)	2 / 143 (1.40%)	
occurrences (all)	1	2	
Infections and infestations			
D0-D28, Nasopharyngitis			
subjects affected / exposed	2 / 129 (1.55%)	2 / 143 (1.40%)	
occurrences (all)	2	2	
D0, D28 Bronchitis			
subjects affected / exposed	0 / 129 (0.00%)	2 / 143 (1.40%)	
occurrences (all)	0	2	
D0-D28, Pharyngitis			

subjects affected / exposed	2 / 129 (1.55%)	0 / 143 (0.00%)	
occurrences (all)	2	0	
D0-D28, Rhinitis			
subjects affected / exposed	2 / 129 (1.55%)	0 / 143 (0.00%)	
occurrences (all)	2	0	

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