Clinical trial results:
Large scale safety study of IMOVAX Polio in selected cities in China, an observational post marketing study

Summary

EudraCT number	2015-005186-23
Trial protocol	Outside EU/EEA
Global end of trial date	12 May 2011

Results information

Result version number	v1 (current)
This version publication date	16 April 2016
First version publication date	16 April 2016

Trial information

Trial identification

Sponsor protocol code	IPV34

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01278433
WHO universal trial number (UTN)	U1111-1115-6566

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur China
Sponsor organisation address	6th floor, No. 112 Jianguo Road, Chaoyang District, Beijing, China, 100022
Public contact	Medical Director, Medical Affairs Department, Sanofi Pasteur China, 86 10-6568 5588, RegistryContactUS@sanofipasteur.com
Scientific contact	Medical Director, Medical Affairs Department, Sanofi Pasteur China, 86 10-6568 5588, RegistryContactUS@sanofipasteur.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	30 October 2011
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 May 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To describe serious adverse events (SAEs) within 30 days after each dose of IMOVAX Polio administered to infants at 2, 3 and 4 months of age and lived in the study cities of China.

Protection of trial subjects:

Only subjects that met all the study inclusion and none of the exclusion criteria were randomized and vaccinated in the study. Vaccinations were performed by qualified and trained study personnel. Subjects with allergy to any of the vaccine components were not vaccinated. After vaccination, subjects were kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment were available on site in case of any immediate allergic reactions.

Background therapy:

Not applicable.

Evidence for comparator:

Not applicable

Actual start date of recruitment	10 December 2010
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	China: 5007
Worldwide total number of subjects	5007
EEA total number of subjects	0

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)	5007
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:

Study subjects were enrolled from 10 December 2010 to 31 July 2011 in clinical centers in China.

Pre-assignment

Screening details:

A total of 5007 subjects who met the inclusion, but none of the exclusion criteria were enrolled and vaccinated.

Period 1

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

Blinding implementation details:

Not applicable.

Arms

Arm title	Study Group

Arm description:

Subjects vaccinated with a primary dose series of IMOVAX Polio at 2, 3 and 4 months of age.

Arm type	Experimental
Investigational medicinal product name	Inactivated Poliomyelitis Vaccine (IMOVAX Polio)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, Intramuscular (IM) injection to the local sites of the anterolateral thigh or upper arm deltoid.

Number of subjects in period 1	Study Group
Started	5007
Completed	4774
Not completed	233
Consent withdrawn by subject	136
Adverse event, non-fatal	5
Lost to follow-up	83
Protocol deviation	9

Baseline characteristics

Reporting groups	
Reporting group title	Overall
Reporting group description:	
Infants subjects receiving IMOVAX Polio vaccine at 2, 3 and 4 months of age.	

Reporting group values	Overall	Total	
Number of subjects	5007	5007	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	5007	5007	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: months			
arithmetic mean	2.3		
standard deviation	± 0.4	-	
Gender categorical Units: Subjects			
Female	2263	2263	
Male	2744	2744	

End points

End points reporting groups

Reporting group title	Study Group

Reporting group description:

Subjects vaccinated with a primary dose series of IMOVAX Polio at 2, 3 and 4 months of age.

Primary: Number of Subjects With All and Related Serious Adverse Events within 30 Days After Any of A Three-Dose Primary Vaccination Series with Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)

End point title	Number of Subjects With All and Related Serious Adverse Events within 30 Days After Any of A Three-Dose Primary Vaccination Series with Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)[1]

End point description:

Occurrence, nature (Medical Dictionary for Regulatory Activities [MedDRA] preferred term), time to onset, duration, outcome, seriousness and relationship to vaccination of any SAEs reported up to 30 days after vaccination and whether the SAE led to early termination from the study.

End point type	Primary

End point timeframe:

30 Days post-any injection

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: Descriptive analyses were performed based on the study groups and the study vaccine administered for this outcome.

End point values	Study Group			
Subject group type	Reporting group			
Number of subjects analysed	5007			
Units: Number				
number (not applicable)				
Total Serious Adverse Events	4			
Upper respiratory tract infection	1			
Flow perceptual pneumonia	2			
Orchitis	1			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Adverse events data were collected from Day 0 (post-vaccination) up to 30 Days post-vaccination.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	13.1

Reporting groups

Reporting group title	Study Group

Reporting group description:

Subjects vaccinated with a primary dose series of IMOVAX Polio at 2, 3 and 4 months of age.

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 primary objective of the study is to solicit and record serious adverse events. Non-serious adverse events were not solicited.

Serious adverse events	Study Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 5007 (0.08%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Respiratory, thoracic and mediastinal disorders			
Flow perceptual pneumonia			
subjects affected / exposed	2 / 5007 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	1 / 5007 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Orchitis			
subjects affected / exposed	1 / 5007 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Study Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 5007 (0.00%)		

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