



## Clinical trial results:

### Clinical Safety Study of the Tdap Combined Vaccine (ADACEL) as a Booster Dose in Healthy Adults and Children in China

#### Summary

EudraCT number	2015-003914-25
Trial protocol	Outside EU/EEA
Global end of trial date	08 October 2013

#### Results information

Result version number	v1 (current)
This version publication date	20 February 2016
First version publication date	20 February 2016

#### Trial information

##### Trial identification

Sponsor protocol code	Td527
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01933776
WHO universal trial number (UTN)	U1111-1127-7738

Notes:

#### Sponsors

Sponsor organisation name	Sanofi Pasteur China
Sponsor organisation address	6th floor, No. 112 Jian Guo Lu, Chaoyang District, Beijing, China, 100022
Public contact	Director, Medical Affairs, Sanofi Pasteur China, 86 10-6568 5588 ex 7312, Jean-Denis.SHU@sanofipasteur.com
Scientific contact	Director, Medical Affairs, Sanofi Pasteur China, 86 10-6568 5588 ex 7312, Jean-Denis.SHU@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	20 November 2013
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	08 October 2013
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To describe the safety in terms of occurrence of serious adverse reactions and Grade 3 adverse reactions after administration of Sanofi Pasteur's Tdap vaccine (ADACEL) given as a single dose in 20 adults and 20 children.

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 also kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment was also available on site in case of any immediate allergic reactions.

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	27 August 2013
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: 40
Worldwide total number of subjects	40
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)	0
Children (2-11 years)	20
Adolescents (12-17 years)	0
Adults (18-64 years)	20

From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

The study subjects were enrolled from 27 August 2013 through 08 October 2013 at 1 clinic center in China.

### Pre-assignment

Screening details:

A total of 40 subjects who met all the inclusion and none of the exclusion criteria were enrolled and vaccinated in this study.

### 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:

Not applicable

### Arms

Are arms mutually exclusive?	Yes
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<b>Arm title</b>	ADACEL™ Vaccine Group 1 (Adults)
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Arm description:

Adults 18 through 64 years of age received a single booster dose of Tdap vaccine (ADACEL™).

Arm type	Experimental
Investigational medicinal product name	Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed -Tdap (Adacel™)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5, intramuscular in the right deltoid, 1 injection of ADACEL on Day 0 (Visit 1).

<b>Arm title</b>	ADACEL™ Vaccine Group 2 (Children)
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Arm description:

Children 4 to 8 years of age received a single booster dose of Tdap vaccine (ADACEL™).

Arm type	Active comparator
Investigational medicinal product name	Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed -Tdap (Adacel™)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5, intramuscular in the right deltoid, 1 injection of ADACEL on Day 0 (Visit 1).

<b>Number of subjects in period 1</b>	ADACEL™ Vaccine Group 1 (Adults)	ADACEL™ Vaccine Group 2 (Children)
Started	20	20
Completed	20	20

## Baseline characteristics

### Reporting groups

Reporting group title	ADACEL™ Vaccine Group 1 (Adults)
Reporting group description: Adults 18 through 64 years of age received a single booster dose of Tdap vaccine (ADACEL™).	
Reporting group title	ADACEL™ Vaccine Group 2 (Children)
Reporting group description: Children 4 to 8 years of age received a single booster dose of Tdap vaccine (ADACEL™).	

Reporting group values	ADACEL™ Vaccine Group 1 (Adults)	ADACEL™ Vaccine Group 2 (Children)	Total
Number of subjects	20	20	40
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	20	20
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	20	0	20
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	44.2	5.8	
standard deviation	± 14.4	± 1.1	-
Gender categorical Units: Subjects			
Female	10	14	24
Male	10	6	16

## End points

### End points reporting groups

Reporting group title	ADACEL™ Vaccine Group 1 (Adults)
Reporting group description:	
Adults 18 through 64 years of age received a single booster dose of Tdap vaccine (ADACEL™).	
Reporting group title	ADACEL™ Vaccine Group 2 (Children)
Reporting group description:	
Children 4 to 8 years of age received a single booster dose of Tdap vaccine (ADACEL™).	

### Primary: Number of Subjects Reporting Serious Adverse Events and Grade 3 Adverse Reactions Following a Single Booster Dose of ADACEL™ Vaccine

End point title	Number of Subjects Reporting Serious Adverse Events and Grade 3 Adverse Reactions Following a Single Booster Dose of ADACEL™ Vaccine <sup>[1]</sup>
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End point description:

Solicited injection site reactions: Pain, Erythema, and Swelling; Solicited systemic reactions: Fever (Temperature), Headache, Malaise, and Myalgia.

China Food and Drug Administration (CFDA)-defined Grade 3 solicited reactions: Pain, Incapacitating, unable to perform usual activities (Children, Group 2) and significant, prevents daily activity (Adults, Group 1); All Participants, Erythema and Swelling, > 30 mm; Fever (Temperature) > 39°C; Headache, Malaise, and Myalgia, Significant, prevents daily activity.

End point type	Primary
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End point timeframe:

Day 0 up to Day 28 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: Descriptive analyses were performed based on the study groups and the study vaccine administered for this outcome.

End point values	ADACEL™ Vaccine Group 1 (Adults)	ADACEL™ Vaccine Group 2 (Children)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: Number of subjects				
number (not applicable)				
Grade 3 Injection site Pain	0	0		
Grade 3 Injection site Erythema	0	3		
Grade 3 Injection site Swelling	0	3		
Grade 3 Fever	0	0		
Grade 3 Headache	0	0		
Grade 3 Malaise	0	0		
Grade 3 Myalgia	0	0		
Serious adverse events	0	0		

## Statistical analyses

No statistical analyses for this end point

## **Secondary: Number of Subjects Reporting a Solicited Injection Site or Systemic Reactions Following A Single Booster Dose of Adacel™ Vaccine**

End point title	Number of Subjects Reporting a Solicited Injection Site or Systemic Reactions Following A Single Booster Dose of Adacel™ Vaccine
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End point description:

Solicited injection site reactions: Pain, Erythema, and Swelling; Solicited systemic reactions: Fever (Temperature), Headache, Malaise, and Myalgia.

China Food and Drug Administration (CFDA)-defined Grade 3 solicited reactions: Pain, Incapacitating, unable to perform usual activities (Children, Group 2) and significant, prevents daily activity (Adults, Group 1); All Participants, Erythema and Swelling, > 30 mm; Fever (Temperature) > 39°C; Headache, Malaise, and Myalgia, Significant, prevents daily activity.

End point type	Secondary
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End point timeframe:

Day 0 up to Day 7 post-vaccination

<b>End point values</b>	ADACEL™ Vaccine Group 1 (Adults)	ADACEL™ Vaccine Group 2 (Children)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: Number of subjects				
number (not applicable)				
Injection site Pain	6	9		
Grade 3 Injection site Pain	0	0		
Injection site Erythema	1	9		
Grade 3 Injection site Erythema	0	3		
Injection site Swelling	3	9		
Grade 3 Injection site Swelling	0	3		
Fever	0	3		
Grade 3 Fever	0	0		
Headache	1	1		
Grade 3 Headache	0	0		
Malaise	0	0		
Grade 3 Malaise	0	0		
Myalgia	1	1		
Grade 3 Myalgia	0	0		

## **Statistical analyses**

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse event data were collected from Day 0 (post-vaccination) up to Day 28 post-vaccination.

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	16
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### Reporting groups

Reporting group title	ADACEL™ Vaccine Group 1 (Adults)
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Reporting group description:

Adults 18 through 64 years of age received a single booster dose of Tdap vaccine (ADACEL™).

Reporting group title	ADACEL™ Vaccine Group 2 (Children)
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Reporting group description:

Children 4 to 8 years of age received a single booster dose of Tdap vaccine (ADACEL™).

Serious adverse events	ADACEL™ Vaccine Group 1 (Adults)	ADACEL™ Vaccine Group 2 (Children)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (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: 5 %

Non-serious adverse events	ADACEL™ Vaccine Group 1 (Adults)	ADACEL™ Vaccine Group 2 (Children)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 20 (30.00%)	9 / 20 (45.00%)	
Nervous system disorders			
Headache			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
General disorders and administration site conditions			
Fever			
alternative assessment type: Systematic			

subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	3 / 20 (15.00%) 3	
Injection site Erythema alternative assessment type: Systematic subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1	9 / 20 (45.00%) 9	
Injection site Pain alternative assessment type: Systematic subjects affected / exposed occurrences (all)	6 / 20 (30.00%) 6	9 / 20 (45.00%) 9	
Injection site Swelling alternative assessment type: Systematic subjects affected / exposed occurrences (all)	3 / 20 (15.00%) 3	9 / 20 (45.00%) 9	
Musculoskeletal and connective tissue disorders Myalgia alternative assessment type: Systematic subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1	1 / 20 (5.00%) 1	
Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	1 / 20 (5.00%) 1	

## **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