EU Clinical Trials Register

Clinical trial results:
Tolerability and Immunogenicity Study of FLUVAL AB Influenza Vaccine (trivalent, seasonal, active ingredient content: 15 gHA/strain/0.5 mL) for the Use in the Season 2013/2014 in Adults and Elderly Subjects

Summary

EudraCT number	2013-002153-30
Trial protocol	HU
Global end of trial date	17 September 2013

Results information

Result version number	v2 (current)
This version publication date	25 June 2017
First version publication date	06 January 2017
Version creation reason	• Correction of full data set • Changes to summary attachments Data correction of data set and summary attachment.
Summary attachment (see zip file)	2013-002153-30-FSR-Synopsis (FluvalAB-H-YL2013 FSR synospis.pdf)

Trial information

Trial identification

Sponsor protocol code	FluvalAB-H-YL2013

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Omninvest Ltd.
Sponsor organisation address	Fő utca 7., Pilisborosjenő, Hungary, H-2097
Public contact	Clinical expert, Fluart Innovative Vaccines Ltd., 36 204197063, jeno.makra@fluart.hu
Scientific contact	Study director, Omninvest Ltd., 36 204197136, brigitta.kozma@omninvest.hu

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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 September 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 September 2013
Global end of trial reached?	Yes
Global end of trial date	17 September 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Aim of this study is to assess immunogenicity and safety of Fluval AB seasonal influenza vaccine with 3 x 15 µgHA active ingredient in two age groups (18-59 years and ≥60 years) in accordance with CPMP/BWP/214/96: "Note for Guidance on Harmonization of Requirements for Influenza Vaccines", 12 March 1997.

Protection of trial subjects:

Only subjects that met all the study inclusion and none of the exclusion criteria were enrolled 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:

-

Evidence for comparator:

-

Actual start date of recruitment	22 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	Hungary: 120
Worldwide total number of subjects	120
EEA total number of subjects	120

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)	0
Adolescents (12-17 years)	0

Adults (18-64 years)	60
From 65 to 84 years	60
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study subjects were enrolled from 22/08/2013 to 17/09/2013 in 3 study center around Budapest, in Hungary.

Pre-assignment

Screening details:

A total of 120 healthy volunteers (males and females) were selected for inclusion in the study, and screened prior to vaccination. All 120 subjects entered the study and were vaccinated (ITT population). 119 subjects attended the control visit at Day 21-28. The data of 119 subjects were available and evaluated at Day 21-28 (PP population).

Period 1

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

Blinding implementation details:

This study was an Phase IV, open label, uncontrolled, multi-centre immunogenicity and tolerability study.

Arms

Arm title	Treatment with Fluval AB trivalent influenza vaccine

Arm description:

Subjects were enrolled in two groups according to age (18-59 years and ≥60 years) and assigned to the following vaccine group:

Adult subject aged 18-59 years:
An adult subject is belonging to age group 18-59 years, if he/she has already been turning 18 but has not yet been turning 60 on the day of vaccination. 15 µgHA/strain/0.5mL of Fluval AB trivalent influenza vaccine was administered once (at Day 0) as a treatment for this age group.

Elderly subject aged ≥60 years:
An elderly subject is belonging to age group ≥60 years, if he/she was turning or has already been turning 60 on the day of vaccination. 15 µgHA/strain/0.5mL of Fluval AB trivalent influenza vaccine was administered once (at Day 0) as a treatment for this age group.

Arm type	Intervention
Investigational medicinal product name	Fluval AB suspension for injection
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Age group 18-59:
Treatment: 15 µgHA/strain/0.5mL of Fluval AB trivalent influenza vaccine was administered once (at Day 0).

Age group ≥60:
Treatment: 15 µgHA/strain/dos of Fluval AB trivalent influenza vaccine was administered once (at Day 0).

Number of subjects in period 1	Treatment with Fluval AB trivalent influenza vaccine
Started	120
Completed	119
Not completed	1
One subject did not attend the visit 2.	1

Baseline characteristics

Reporting groups

Reporting group title	Overall trial

Reporting group description:

Max. 120 healthy volunteers of full contractual capacity were planned to be enrolled in two age groups (18 to 59 years and ≥60 years) from both sexes to ensure a study population of at least 50-50 evaluable cases in each age group.

Adults aged 18-59 years: Screened: 60 healthy volunteers of full contractual capacity from both sexes. PP population: 59 persons.

Elderly aged ≥60 years: Screened: 60 healthy volunteers of full contractual capacity from both sexes. PP population: 60 persons.

Reporting group values	Overall trial	Total	
Number of subjects	120	120	
Age categorical			
Adult subject aged 18-59 years: An adult subject is belonging to age group 18-59 years, if he/she has already been turning 18 but has not yet been turning 60 on the day of vaccination. Elderly subject aged ≥60 years: An elderly subject is belonging to age group ≥60 years, if he/she was turning or has already been turning 60 on the day of vaccination.			
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)	0	0	
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	
Adults (aged 18-59 years)	60	60	
Elderly (aged over 60 years	60	60	
Age continuous			
Descriptive statistics (mean, standard deviation, median, minimum and maximum) for age at enrolment are calculated overall and by age group.			
Units: years			
geometric mean	58.1		
standard deviation	± 14.5	-	
Gender categorical			
Distributions of subjects by sex are summarized overall			
Units: Subjects			
Female	69	69	
Male	51	51	

End points

End points reporting groups

Reporting group title	Treatment with Fluval AB trivalent influenza vaccine

Reporting group description:

Subjects were enrolled in two groups according to age (18-59 years and ≥60 years) and assigned to the following vaccine group:

Adult subject aged 18-59 years:
An adult subject is belonging to age group 18-59 years, if he/she has already been turning 18 but has not yet been turning 60 on the day of vaccination. 15 µgHA/strain/0.5mL of Fluval AB trivalent influenza vaccine was administered once (at Day 0) as a treatment for this age group.

Elderly subject aged ≥60 years:
An elderly subject is belonging to age group ≥60 years, if he/she was turning or has already been turning 60 on the day of vaccination. 15 µgHA/strain/0.5mL of Fluval AB trivalent influenza vaccine was administered once (at Day 0) as a treatment for this age group.

Primary: Geometric Mean Titers (GMTs) of influenza Antibodies Before and After Vaccination in subjects aged 18-59 years

End point title	Geometric Mean Titers (GMTs) of influenza Antibodies Before and After Vaccination in subjects aged 18-59 years[1]

End point description:

Anti-hemagglutinin antibody titers were measured for each strain by Hemagglutination Inhibition (HI) test. The GMTs were determined by HI titer.

End point type	Primary

End point timeframe:

Day 0 (pre-vaccination) and Day 21-28 (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 analysis was performed based on the study group and the study vaccine administered for this outcome.

End point values	Treatment with Fluval AB trivalent influenza vaccine			
Subject group type	Reporting group			
Number of subjects analysed	59[2]			
Units: Titers (1/dil)				
number (confidence interval 95%)				
A/H1N1; Day 0	49.1 (37.4 to 64.6)			
A/H1N1; Day 21	154 (119 to 198)			
A/H3N2; Day 0	92.7 (69.7 to 123)			
A/H3N2; Day 21	331 (264 to 416)			
B/; Day 0	17.7 (13.6 to 23)			
B/; Day 21	63.2 (50.9 to 78.5)			

Notes:

[2] - PP population in this age group were 59 persons.

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers (GMTs) of influenza Antibodies Before and After Vaccination in subjects aged over 60 years

End point title	Geometric Mean Titers (GMTs) of influenza Antibodies Before and After Vaccination in subjects aged over 60 years[3]

End point description:

Anti-hemagglutinin antibody titers were measured for each strain by Hemagglutination Inhibition (HI) test. The GMTs were determined by HI titer.

End point type	Primary

End point timeframe:

Day 0 (pre-vaccination) and Day 21-28 (post-vaccination)

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: Descriptive analysis was performed based on the study group and the study vaccine administered for this outcome.

End point values	Treatment with Fluval AB trivalent influenza vaccine			
Subject group type	Reporting group			
Number of subjects analysed	60[4]			
Units: Titers (1/dil)				
number (confidence interval 95%)				
A/H1N1; Day 0	34.4 (27.9 to 42.4)			
A/H1N1; Day 21	109 (88.4 to 135)			
A/H3N2; Day 0	80 (62.5 to 102)			
A/H3N2; Day 21	309 (248 to 386)			
B/; Day 0	11.1 (8.75 to 14.1)			
B/; Day 21	47.6 (36.9 to 61.4)			

Notes:

[4] - PP population in this age group were 60 persons.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Aged 18-59 years With Seroconversion Against

Influenza Antigens After the Vaccination

End point title	Percentage of Subjects Aged 18-59 years With Seroconversion Against Influenza Antigens After the Vaccination[5]

End point description:

Anti-hemagglutinin antibody titers were measured for each strain by Hemagglutination Inhibition (HI) test. Seroconversion was defined as the proportion of subjects with a pre-vaccination titer < 10 (1/dil) to a post-vaccination titer ≥ 40 (1/dil). Significant increase was defined as proportion of subjects with a pre- vaccination titer ≥ 10 (1/dil) and ≥ 4-fold increase of the titer.

End point type	Primary

End point timeframe:

Day 21-28 post-vaccination/Day 0 (pre-vaccination)

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: Descriptive analysis was performed based on the study group and the study vaccine administered for this outcome.

End point values	Treatment with Fluval AB trivalent influenza vaccine			
Subject group type	Reporting group			
Number of subjects analysed	59[6]			
Units: Subject percentage				
number (confidence interval 95%)				
A/H1N1; Day 21	59.3 (45.7 to 71.9)			
A/H3N2; Day21	69.5 (56.1 to 80.8)			
B/; Day 21	54.2 (40.8 to 67.3)			

Notes:

[6] - PP population in this age group were 59 persons.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Aged ove 60 years With Seroconversion Against Influenza Antigens After the Vaccination

End point title	Percentage of Subjects Aged ove 60 years With Seroconversion Against Influenza Antigens After the Vaccination[7]

End point description:

Anti-hemagglutinin antibody titers were measured for each strain by Hemagglutination Inhibition (HI) test. Seroconversion was defined as the proportion of subjects with a pre-vaccination titer < 10 (1/dil) to a post-vaccination titer ≥ 40 (1/dil). Significant increase was defined as proportion of subjects with a pre- vaccination titer ≥ 10 (1/dil) and ≥ 4-fold increase of the titer.

End point type	Primary

End point timeframe:

Day 21-28 post-vaccination/Day 0 (pre-vaccination)

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: Descriptive analysis was performed based on the study group and the study vaccine administered for this outcome.

End point values	Treatment with Fluval AB trivalent influenza vaccine			
Subject group type	Reporting group			
Number of subjects analysed	60[8]			
Units: Subject percentage				
number (confidence interval 95%)				
A/H1N1; Day 21	66.7 (53.3 to 78.3)			
A/H3N2; Day 21	70 (56.8 to 81.2)			
B/; Day 21	65 (51.6 to 76.9)			

Notes:

[8] - PP population in this age group were 60 persons.

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titer Ratios (GMTRs) of influenza Antibodies After Vaccination in subjects aged 18-59 years

End point title	Geometric Mean Titer Ratios (GMTRs) of influenza Antibodies After Vaccination in subjects aged 18-59 years[9]

End point description:

Anti-hemagglutinin antibody titers were measured for each strain by Hemagglutination Inhibition (HI) test. The GMTs were determined by HI titer.

End point type	Primary

End point timeframe:

Day 21 post-vaccination/Day 0 (pre-vaccination)

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: Descriptive analysis was performed based on the study group and the study vaccine administered for this outcome.

End point values	Treatment with Fluval AB trivalent influenza vaccine			
Subject group type	Reporting group			
Number of subjects analysed	59[10]			
Units: Titer ratios (1/dil)				
geometric mean (confidence interval 95%)				
A/H1N1	3.13 (2.63 to 3.72)			
A/H3N2	3.58 (2.92 to 4.38)			
B/	3.58 (2.96 to 4.32)			

Notes:

[10] - PP population in this age group were 59 persons.

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titer Ratios (GMTRs) of influenza Antibodies After Vaccination in subjects aged over 60 years

End point title	Geometric Mean Titer Ratios (GMTRs) of influenza Antibodies After Vaccination in subjects aged over 60 years[11]
End point description:	
Anti-hemagglutinin antibody titers were measured for each strain by Hemagglutination Inhibition (HI) test. The GMTs were determined by HI titer.	
End point type	Primary
End point timeframe:	
Day 21 post-vaccination/Day 0 (pre-vaccination)	

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: Descriptive analysis was performed based on the study group and the study vaccine administered for this outcome.

End point values	Treatment with Fluval AB trivalent influenza vaccine			
Subject group type	Reporting group			
Number of subjects analysed	60[12]			
Units: Titer ratios (1/dil)				
geometric mean (confidence interval 95%)				
A/H1N1	3.17 (2.65 to 3.8)			
A/H3N2	3.86 (3.19 to 4.68)			
B/	4.29 (3.45 to 5.33)			

Notes:

[12] - PP population in this age group were 60 persons.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Aged 18 to 59 Years With Seroprotection Against Influenza Antigens Before and After Vaccination

End point title	Percentage of Subjects Aged 18 to 59 Years With Seroprotection Against Influenza Antigens Before and After Vaccination[13]
End point description:	
Anti-hemagglutinin antibody titers were measured for each strain by Hemagglutination Inhibition (HI) test. Seroprotection was defined as antibody titers ≥ 40 (1/dil).	
End point type	Primary
End point timeframe:	
Day 0 (pre-vaccination to Day 21-28 (post-vaccination)	

Notes:

[13] - 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 analysis was performed based on the study group and the study vaccine administered for this outcome.

End point values	Treatment with Fluval AB trivalent influenza vaccine			
Subject group type	Reporting group			
Number of subjects analysed	59[14]			
Units: Subject percentage				
number (confidence interval 95%)				
A/H1N1; Day 0	69.5 (56.1 to 80.8)			
A/H1N1; Day 21	94.9 (85.9 to 98.9)			
A/H3N2; Day 0	88.1 (77.1 to 95.1)			
A/H3N2; Day 21	100 (93.9 to 100)			
B/; Day 0	30.5 (19.2 to 43.9)			
B/; Day 21	79.7 (67.2 to 89)			

Notes:

[14] - PP population in this age group were 59 persons.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Aged over 60 Years With Seroprotection Against Influenza Antigens Before and After Vaccination

End point title	Percentage of Subjects Aged over 60 Years With Seroprotection Against Influenza Antigens Before and After Vaccination[15]

End point description:

Anti-hemagglutinin antibody titers were measured for each strain by Hemagglutination Inhibition (HI) test. Seroprotection was defined as antibody titers ≥ 40 (1/dil).

End point type	Primary

End point timeframe:

Day 0 (pre-vaccination) and Day 21-28 post-vaccination

Notes:

[15] - 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 analysis was performed based on the study group and the study vaccine administered for this outcome.

End point values	Treatment with Fluval AB trivalent influenza vaccine			
Subject group type	Reporting group			
Number of subjects analysed	60[16]			
Units: Percentage of subjects				

number (confidence interval 95%)					
A/H1N1; Day 0	51.7 (38.4 to 64.8)				
A/H1N1; Day 21	96.7 (88.5 to 99.6)				
A/H3N2; Day 0	88.3 (77.4 to 95.2)				
A/H3N2; Day 21	100 (94 to 100)				
B/; Day 0	18.3 (9.52 to 30.4)				
B/; Day 21	78.3 (65.8 to 87.9)				

Notes:

[16] - PP population in this age group were 60 persons.

Statistical analyses

No statistical analyses for this end point

Primary: Proportion of subjects seroconverted or had a significant increase in titres in subjects aged 18-59 years

End point title	Proportion of subjects seroconverted or had a significant increase in titres in subjects aged 18-59 years[17]

End point description:

Criteria: number of seroconversions or significant increase in antihaemagglutinin antibody titre >40%

End point type	Primary

End point timeframe:

From Day 0 (pre-vaccination) to Day 21-28 (post-vaccination).

Notes:

[17] - 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 analysis was performed based on the study group and the study vaccine administered for this outcome.

End point values	Treatment with Fluval AB trivalent influenza vaccine			
Subject group type	Reporting group			
Number of subjects analysed	119			
Units: Percentage of subjects				
A/H1N1	59			
A/H3N2	69			
B/	54			

Statistical analyses

No statistical analyses for this end point

Primary: Increase in GMT in subjects aged 18-59 years

End point title	Increase in GMT in subjects aged 18-59 years[18]

End point description:

Criteria: mean geometric increase of antihaemagglutinin antibody titres: >2.5.

End point type	Primary

End point timeframe:

From Day 0 (pre-vaccination) to Day 21-28 (postvaccination).

Notes:

[18] - 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 analysis was performed based on the study group and the study vaccine administered for this outcome.

End point values	Treatment with Fluval AB trivalent influenza vaccine			
Subject group type	Reporting group			
Number of subjects analysed	59[19]			
Units: unit(s)				
number (not applicable)				
A/H1N1	3.1			
A/H3N2	3.6			
B/	3.6			

Notes:

[19] - PP population in this age group were 59 persons.

Statistical analyses

No statistical analyses for this end point

Primary: Proportion of subjects seroprotected in subjects aged 18-59 years

End point title	Proportion of subjects seroprotected in subjects aged 18-59 years[20]

End point description:

Criteria: The proportion of subjects achieving an antihaemagglutinin antibody titre ≥40 should be >70%.

End point type	Primary

End point timeframe:

From Day 0 (pre-vaccination) to Day 21-28 (postvaccination)

Notes:

[20] - 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 analysis was performed based on the study group and the study vaccine administered for this outcome.

End point values	Treatment with Fluval AB trivalent influenza vaccine			
Subject group type	Reporting group			
Number of subjects analysed	59[21]			
Units: Percentage of subjects				
A/H1N1	95			
A/H3N2	100			
B/	80			

Notes:

[21] - PP population in this age group were 59 persons.

Statistical analyses

No statistical analyses for this end point

Primary: Proportion of subjects seroconverted or had a significant increase in titres in subjects aged over 60 years

End point title	Proportion of subjects seroconverted or had a significant increase in titres in subjects aged over 60 years[22]

End point description:

Criteria: Number of seroconversions or significant increase in antihaemagglutinin antibody titre > 30 %

End point type	Primary

End point timeframe:

From Day 0 (pre-vaccination) to Day21-28 (postvaccination).

Notes:

[22] - 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 analysis was performed based on the study group and the study vaccine administered for this outcome.

End point values	Treatment with Fluval AB trivalent influenza vaccine			
Subject group type	Reporting group			
Number of subjects analysed	60[23]			
Units: Percentage of subjects				
A/H1N1	67			
A/H3N2	70			
B/	65			

Notes:

[23] - PP population in this age group were 60 persons.

Statistical analyses

No statistical analyses for this end point

Primary: Increase in GMT in subjects aged over 60 years

End point title	Increase in GMT in subjects aged over 60 years[24]

End point description:

Criteria: Mean geometric increase of antihaemagglutinin antibody titres: > 2.0

End point type	Primary

End point timeframe:

From Day 0 (pre-vaccination) to Day 21-28 (post vaccination).

Notes:

[24] - 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 analysis was performed based on the study group and the study vaccine administered for this outcome.

End point values	Treatment with Fluval AB trivalent influenza vaccine			
Subject group type	Reporting group			
Number of subjects analysed	60[25]			
Units: unit(s)				
number (not applicable)				
A/H1N1	3.2			
A/H3N2	3.9			
B/	4.3			

Notes:

[25] - PP population in this age group were 60 persons.

Statistical analyses

No statistical analyses for this end point

Primary: Proportion of subjects seroprotected in subjects aged over 60 years

End point title	Proportion of subjects seroprotected in subjects aged over 60 years[26]

End point description:

Criteria: The proportion of subjects achieving an antihaemagglutinin antibody titre ≥40 should be > 60 %.

End point type	Primary

End point timeframe:

From Day 0 (pre-vaccination) to Day 21-28 (post vaccination).

Notes:

[26] - 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 analysis was performed based on the study group and the study vaccine administered for this outcome.

End point values	Treatment with Fluval AB trivalent influenza vaccine			
Subject group type	Reporting group			
Number of subjects analysed	60[27]			
Units: Percentage of subjects				
A/H1N1	97			
A/H3N2	100			
B/	78			

Notes:

[27] - PP population in this age group were 60 persons.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Day 0 (pre-vaccination) to Day 21-28 (post vaccination).

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14

Reporting groups

Reporting group title	Treatment group

Reporting group description: -

Serious adverse events	Treatment group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 120 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Treatment group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 120 (27.50%)		
Nervous system disorders			
Headache	Additional description: 4 of them were not related to the study vaccine according to the investigators.		
subjects affected / exposed	8 / 120 (6.67%)		
occurrences (all)	8		
General disorders and administration site conditions			
Vaccination site pain			
subjects affected / exposed	23 / 120 (19.17%)		
occurrences (all)	23		
Vaccination site erythema			
subjects affected / exposed	16 / 120 (13.33%)		
occurrences (all)	16		
Vaccination site induration			

subjects affected / exposed	12 / 120 (10.00%)		
occurrences (all)	12		
Vaccination site swelling			
subjects affected / exposed	14 / 120 (11.67%)		
occurrences (all)	14		
Vaccination site haematoma			
subjects affected / exposed	2 / 120 (1.67%)		
occurrences (all)	2		
Hyperhydrosis			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Malaise	Additional description: 2 of them were not related to the study vaccine according to the investigators.		
subjects affected / exposed	4 / 120 (3.33%)		
occurrences (all)	4		
Pyrexia			
subjects affected / exposed	2 / 120 (1.67%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
Myalgia	Additional description: 1 of them was not related to the study vaccine according to the investigators.		
subjects affected / exposed	4 / 120 (3.33%)		
occurrences (all)	4		
Arthralgia			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		

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