Clinical trial results:
A randomised, double-blind, placebo-controlled study to assess the safety, tolerability, efficacy and immunogenicity of an influenza A vaccine (Vaccine FP-01.1) in healthy volunteers following virus challenge

Summary

EudraCT number	2013-004612-22
Trial protocol	GB
Global end of trial date	27 November 2014

Results information

Result version number	v1 (current)
This version publication date	26 March 2016
First version publication date	26 March 2016

Trial information

Trial identification

Sponsor protocol code	FP-01.1_CS_04

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Altimmune UK Ltd, previously known as Immune Targeting Systems Ltd
Sponsor organisation address	London Bioscience Innovation Centre, 2 Royal College Street, London, United Kingdom, NW1 0NH
Public contact	General contact point, Altimmune UK Ltd, previously known as Immune Targeting Systems Ltd, +44 02076914908, info@altimmune.com
Scientific contact	General contact point, Altimmune UK Ltd, previously known as Immune Targeting Systems Ltd, +44 02076914908, info@altimmune.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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	24 December 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 November 2014
Global end of trial reached?	Yes
Global end of trial date	27 November 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to further characterise the safety and tolerability profile of Vaccine FP-01.1.

Protection of trial subjects:

The study was conducted in accordance with Good Clinical Practice as required by the International Conference on Harmonisation guidelines and in accordance with country-specific laws and regulations governing clinical studies of investigational products. A study-specific informed consent document was signed by the subject and the investigator before any study-related procedures were performed. A separate consent form was also provided for optional exploratory genomics research.

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	29 January 2014
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	United Kingdom: 111
Worldwide total number of subjects	111
EEA total number of subjects	111

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)	111
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The first subject was enrolled on 29 January 2014, and the last subject last visit occurred on 27 November 2014

Pre-assignment

Screening details:

Potential subjects first underwent panel screening (Study Visit 1) to demonstrate good health and acceptable haemagglutination inhibition titre to the challenge H1N1 virus. After completion of the panel screening, potential subjects underwent a protocol-specific screening to confirm eligibility (Study Visit 2, Days -28 to -2).

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Blinding implementation details:

With the exception of the pharmacy department, the statistician preparing the randomisation to Vaccine FP-01.1/placebo, the member(s) of staff administering Vaccine FP-01.1/placebo and quality assurance auditors where necessary, all clinical and non-clinical staff remained blinded to the treatment allocation until after the database was locked.

Arms

Are arms mutually exclusive?	Yes
Arm title	Vaccine FP-01.1

Arm description:

Subjects who received 2 vaccinations of Vaccine FP-01.1, and were otherwise eligible, who were administered a single dose of the H1N1 challenge virus in the morning of Day C1 (Study Day 44).

All subjects who were administered the challenge virus were given a 5-day course of Tamiflu, which was administered orally (75 mg twice daily; 10 capsules in total). The first dose was given to subjects in the evening of Day C7.

Arm type	Experimental
Investigational medicinal product name	Vaccine FP-01.1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 2 single doses of 250 µg/peptide Vaccine FP-01.1 (total 1.5 mg peptide). The first dose was administered on Day 1 and the second dose approximately 4 weeks later, on Day 29.

Each dose of Vaccine FP-01.1 was administered as an IM injection (0.5 mL) in the deltoid muscle of the non-dominant arm by appropriately trained clinic staff members.

Arm title	Placebo

Arm description:

Subjects who received 2 doses of placebo, and were otherwise eligible, who were administered a single dose of the H1N1 challenge virus in the morning of Day C1 (Study Day 44).

All subjects who were administered the challenge virus were given a 5-day course of Tamiflu, which was administered orally (75 mg twice daily; 10 capsules in total). The first dose was given to subjects in the evening of Day C7.

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 2 single doses of corresponding placebo for Vaccine FP-01.1. The first dose was administered on Day 1 and the second dose approximately 4 weeks later, on Day 29.

Each dose of placebo was administered as an IM injection (0.5 mL) in the deltoid muscle of the non-dominant arm by appropriately trained clinic staff members.

Number of subjects in period 1	Vaccine FP-01.1	Placebo
Started	57	54
Start of vaccination phase (Day 1)	57	54
End of vaccination phase (Day C-1)	42	41
Start of virus challenge phase (Day 44)	42	41
End of virus challenge phase (Day 72)	42	41
Final follow-up (Day 209)	42	40
Completed	42	40
Not completed	15	14
Egg allergy	1	-
Physician decision	1	-
Consent withdrawn by subject	3	2
Adverse event, non-fatal	4	1
Day 29 H1N1 results out of range	4	7
Out of range safety laboratory results on Day C-1	1	-
Lost to follow-up	-	1
Lack of response from subject's GP	-	3
Protocol deviation	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Vaccine FP-01.1

Reporting group description:

Subjects who received 2 vaccinations of Vaccine FP-01.1, and were otherwise eligible, who were administered a single dose of the H1N1 challenge virus in the morning of Day C1 (Study Day 44).

All subjects who were administered the challenge virus were given a 5-day course of Tamiflu, which was administered orally (75 mg twice daily; 10 capsules in total). The first dose was given to subjects in the evening of Day C7.

Reporting group title	Placebo

Reporting group description:

Subjects who received 2 doses of placebo, and were otherwise eligible, who were administered a single dose of the H1N1 challenge virus in the morning of Day C1 (Study Day 44).

All subjects who were administered the challenge virus were given a 5-day course of Tamiflu, which was administered orally (75 mg twice daily; 10 capsules in total). The first dose was given to subjects in the evening of Day C7.

Reporting group values	Vaccine FP-01.1	Placebo	Total
Number of subjects	57	54	111
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	31.6	33.6	
standard deviation	± 6.54	± 7.12	-
Gender categorical Units: Subjects			
Female	24	31	55
Male	33	23	56
Race Units: Subjects			
Asian	1	4	5
Black or African American	6	1	7
Mixed race - White and Black	0	1	1
Mixed race - White and Black Caribbean	1	0	1
White	49	47	96
Zimbabwean	0	1	1
Ethnicity Units: Subjects			
Hispanic	1	3	4
Non-Hispanic	56	51	107
Height Units: cm			
arithmetic mean	173.11	170.12	
standard deviation	± 9.274	± 8.458	-
Weight Units: kg			

arithmetic mean	74.51	71.07	
standard deviation	± 13.885	± 9.769	-
Body Mass Index			
Units: kg per square metre			
arithmetic mean	24.713	24.528	
standard deviation	± 3.249	± 2.651	-

End points

End points reporting groups

Reporting group title	Vaccine FP-01.1

Reporting group description:

Subjects who received 2 vaccinations of Vaccine FP-01.1, and were otherwise eligible, who were administered a single dose of the H1N1 challenge virus in the morning of Day C1 (Study Day 44).

All subjects who were administered the challenge virus were given a 5-day course of Tamiflu, which was administered orally (75 mg twice daily; 10 capsules in total). The first dose was given to subjects in the evening of Day C7.

Reporting group title	Placebo

Reporting group description:

Subjects who received 2 doses of placebo, and were otherwise eligible, who were administered a single dose of the H1N1 challenge virus in the morning of Day C1 (Study Day 44).

All subjects who were administered the challenge virus were given a 5-day course of Tamiflu, which was administered orally (75 mg twice daily; 10 capsules in total). The first dose was given to subjects in the evening of Day C7.

Primary: Adverse event profile

End point title	Adverse event profile[1]

End point description:

Overall summary of all adverse events for both treatment groups.

End point type	Primary

End point timeframe:

Entire duration of study

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 primary objective of this study was to further characterise the safety and tolerability profile of Vaccine FP-01.1. Descriptive data are reported for the specified safety parameters.

End point values	Vaccine FP-01.1	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	54		
Units: Number of subjects				
Adverse event	39	30		
Treatment-emergent adverse event	38	30		
Serious adverse event	1	1		
Adverse event leading to withdrawal	4	1		
Adverse event leading to death	0	0		
Severe adverse event	2	3		
Treatment-related treatment-emergent adverse event	14	4		

Statistical analyses

No statistical analyses for this end point

Primary: Abnormal clinical laboratory values

End point title	Abnormal clinical laboratory values[2]

End point description:

Number of subjects with abnormal clinical laboratory value for listed parameter in either the vaccination phase or the virus challenge phase

End point type	Primary

End point timeframe:

Entire duration of study

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: The primary objective of this study was to further characterise the safety and tolerability profile of Vaccine FP-01.1. Descriptive data are reported for the specified safety parameters.

End point values	Vaccine FP-01.1	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	54		
Units: Number of subjects				
Cotinine	1	0		
C Reactive Protein	1	1		
Leukocytes	1	0		
Neutrophils	1	0		
Total	2	1		

Statistical analyses

No statistical analyses for this end point

Primary: Local injection site reaction - Day 1

End point title	Local injection site reaction - Day 1[3]

End point description:

Injection site reaction of any severity

End point type	Primary

End point timeframe:

0.5h 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: The primary objective of this study was to further characterise the safety and tolerability profile of Vaccine FP-01.1. Descriptive data are reported for the specified safety parameters.

End point values	Vaccine FP-01.1	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	54		
Units: Number of subjects				
Pain	35	3		
Erythema/redness	8	2		

Bruising	0	0		
Induration/swelling	4	0		
Itching	0	0		
Other	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Local injection site reaction - Day 29

End point title	Local injection site reaction - Day 29[4]

End point description:

Injection site reaction of any severity

End point type	Primary

End point timeframe:

0.5h post-vaccination

Notes:

[4] - 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 primary objective of this study was to further characterise the safety and tolerability profile of Vaccine FP-01.1. Descriptive data are reported for the specified safety parameters.

End point values	Vaccine FP-01.1	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	53		
Units: Number of subjects				
Pain	16	1		
Erythema/redness	5	0		
Bruising	0	0		
Induration/swelling	0	0		
Itching	0	0		
Other	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Laboratory-confirmed illness

End point title	Laboratory-confirmed illness

End point description:

Incidence of laboratory-confirmed illness during the efficacy assessment period

End point type	Secondary

End point timeframe:

During efficacy assessment period (from first assessment after virus challenge until last assessment prior to administration of Tamiflu)

End point values	Vaccine FP-01.1	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	41		
Units: Number of subjects				
Laboratory-confirmed mild illness	26	22		
Laboratory-confirmed moderate illness	10	11		

Statistical analyses

Statistical analysis title	Laboratory-confirmed mild illness
Comparison groups	Vaccine FP-01.1 v Placebo
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.5904 [5]
Method	Pearson's chi-square test

Notes:

[5] - P-value from Pearson's chi-square test with Yates's correction

Statistical analysis title	Laboratory-confirmed moderate illness
Comparison groups	Vaccine FP-01.1 v Placebo
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.9491 [6]
Method	Pearson's chi-square test

Notes:

[6] - P-value from Pearson's chi-square test with Yates's correction

Secondary: Incidence of symptoms and signs of influenza-like illness

End point title	Incidence of symptoms and signs of influenza-like illness

End point description:

Incidence and severity of symptoms and signs of influenza-like illness and pyrexia during the efficacy assessment period

End point type	Secondary

End point timeframe:

During efficacy assessment period (from first assessment after virus challenge until last assessment prior to administration of Tamiflu)

End point values	Vaccine FP-01.1	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	41		
Units: Number of subjects				
Any mild or worse symptom or sign or pyrexia	38	31		
Any moderate or worse symptom or sign or pyrexia	10	13		

Statistical analyses

Statistical analysis title	Any mild or worse symptom or sign or pyrexia
Comparison groups	Placebo v Vaccine FP-01.1
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.1297 [7]
Method	Pearson's chi-square test

Notes:

[7] - P-value from Pearson's chi-square test with Yates's correction.

Statistical analysis title	Any moderate or worse symptom or sign or pyrexia
Comparison groups	Placebo v Vaccine FP-01.1
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.5765 [8]
Method	Pearson's chi-square test

Notes:

[8] - P-value from Pearson's chi-square test with Yates's correction.

Secondary: Duration of signs and symptoms of influenza-like illness

End point title	Duration of signs and symptoms of influenza-like illness

End point description:

Number of days subjects experienced signs and symptoms of influenza-like illness and pyrexia

End point type	Secondary

End point timeframe:

During efficacy assessment period (from first assessment after virus challenge until last assessment prior to administration of Tamiflu)

End point values	Vaccine FP-01.1	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	41		
Units: Number of days				
arithmetic mean (standard deviation)				
Mild or worse sign or symptom or pyrexia	2.86 (± 1.98)	2.68 (± 2.31)		
Moderate or worse sign or symptom or pyrexia	0.5 (± 1.09)	0.59 (± 1.14)		

Statistical analyses

Statistical analysis title	Mild or worse symptoms, signs, and pyrexia
Comparison groups	Vaccine FP-01.1 v Placebo
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.6346
Method	Mann-Whitney non-parametric test

Statistical analysis title	Moderate or worse symptoms, signs, and pyrexia
Comparison groups	Vaccine FP-01.1 v Placebo
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.5168
Method	Mann-Whitney non-parametric test

Secondary: Incidence of viral shedding

End point title	Incidence of viral shedding

End point description:

Incidence of virus shedding as determined by reverse transcription polymerase chain reaction (RT-PCR) or tissue culture infectivity (TCI)

End point type	Secondary

End point timeframe:

During efficacy assessment period (from first assessment after virus challenge until last assessment prior to administration of Tamiflu)

End point values	Vaccine FP-01.1	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	41		
Units: Number of subjects				
Virus shedding by RT-PCR or TCI	28	27		
Virus shedding by RT-PCR	28	27		
Virus shedding by TCI	23	26		

Statistical analyses

Statistical analysis title	Virus shedding by RT-PCR or TCI
Comparison groups	Vaccine FP-01.1 v Placebo
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 1 [9]
Method	Pearson's chi-square test

Notes:

[9] - Pearson's chi-square test with Yates's correction

Statistical analysis title	Virus shedding by RT-PCR
Comparison groups	Vaccine FP-01.1 v Placebo
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 1 [10]
Method	Pearson's chi-square test

Notes:

[10] - Pearson's chi-square test with Yates's correction

Statistical analysis title	Virus shedding by TCI
Comparison groups	Vaccine FP-01.1 v Placebo
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.5631 [11]
Method	Pearson's chi-square test

Notes:

[11] - Pearson's chi-square test with Yates's correction

Secondary: Duration of viral shedding

End point title	Duration of viral shedding

End point description:

Number of days demonstrating virus shedding as determined by reverse transcription polymerase chain reaction (RT-PCR) or tissue culture infectivity (TCI)

End point type	Secondary

End point timeframe:

During efficacy assessment period (from first assessment after virus challenge until last assessment prior to administration of Tamiflu)

End point values	Vaccine FP-01.1	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	41		
Units: Number of days				
arithmetic mean (standard deviation)				
Virus shedding by RT-PCR or TCI	2.57 (± 2.25)	2.71 (± 2.25)		
Virus shedding by RT-PCR	2.57 (± 2.25)	2.71 (± 2.25)		
Virus shedding by TCI	2.1 (± 2.2)	2.24 (± 1.95)		

Statistical analyses

Statistical analysis title	Virus shedding by RT-PCR or TCI
Comparison groups	Vaccine FP-01.1 v Placebo
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.8224 [12]
Method	Mann-Whitney non-parametric test

Notes:

[12] - P-value from Mann-Whitney non-parametric test.

Statistical analysis title	Virus shedding by RT-PCR
Comparison groups	Vaccine FP-01.1 v Placebo
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.8224 [13]
Method	Mann-Whitney non-parametric test

Notes:

[13] - P-value from Mann-Whitney non-parametric test.

Statistical analysis title	Virus shedding by TCI
Comparison groups	Vaccine FP-01.1 v Placebo
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.6826 [14]
Method	Mann-Whitney non-parametric test

Notes:

[14] - P-value from Mann-Whitney non-parametric test.

Secondary: Immunogenicity (interferon-gamma ELISPOT score)

End point title	Immunogenicity (interferon-gamma ELISPOT score)

End point description:

Interferon-gamma enzyme-linked immunosorbent spot (ELISPOT) score , for sum of the six individual long peptides comprising FP-01.1, after incubation of peripheral blood mononuclear cells isolated from subject blood samples with these peptides

End point type	Secondary

End point timeframe:

Comparison between baseline (ie prior to first injection of vaccine/placebo) and day before virus challenge

End point values	Vaccine FP-01.1	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	52		
Units: ELISPOT score				
median (full range (min-max))				
Baseline	87 (0 to 788)	66 (0 to 1146)		
Day before virus challenge (Day C-1)	363 (0 to 1261)	134 (0 to 733)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All adverse events (AEs) were recorded throughout the entire study period, from study-specific screening (Visit 2) to final follow-up visit (Day 209).

Adverse event reporting additional description:

Solicited (collected via subject score cards) and unsolicited (collected via targeted physical examination) symptoms and signs of influenza were not routinely reported as AEs, as these were study efficacy endpoints, unless there was a reason to do so. Injection site reactions graded as moderate or severe were recorded as AEs.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	FP-01.1 - Vaccination phase

Reporting group description:

AEs occurring during vaccination phase - Day 1 to Day C1 - for subjects who received FP-01.1

Reporting group title	Placebo - Vaccination phase

Reporting group description:

AEs occurring during vaccination phase - Day 1 to Day C1 - for subjects who received placebo

Reporting group title	FP-01.1 - Virus challenge phase

Reporting group description:

AEs occurring during virus challenge phase - Day C1 to Day C29 - for subjects who received FP-01.1

Reporting group title	Placebo - Virus challenge phase

Reporting group description:

AEs occurring during virus challenge phase - Day C1 to Day C29 - for subjects who received placebo

Reporting group title	FP-01.1 - Follow-up

Reporting group description:

AEs occurring during follow-up phase - Day C29 to Day C209 - for subjects who received FP-01.1

Reporting group title	Placebo - Follow-up

Reporting group description:

AEs occurring during follow-up phase - Day C29 to Day C209 - for subjects who received placebo

Serious adverse events	FP-01.1 - Vaccination phase	Placebo - Vaccination phase	FP-01.1 - Virus challenge phase
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			

subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo - Virus challenge phase	FP-01.1 - Follow-up	Placebo - Follow-up
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 41 (0.00%)	1 / 57 (1.75%)	1 / 54 (1.85%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			
subjects affected / exposed	0 / 41 (0.00%)	1 / 57 (1.75%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	FP-01.1 - Vaccination phase	Placebo - Vaccination phase	FP-01.1 - Virus challenge phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 57 (45.61%)	12 / 54 (22.22%)	19 / 42 (45.24%)
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	6 / 57 (10.53%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	6	0	0
Influenza like illness			

subjects affected / exposed	0 / 57 (0.00%)	2 / 54 (3.70%)	1 / 42 (2.38%)
occurrences (all)	0	2	1
Fatigue			
subjects affected / exposed	0 / 57 (0.00%)	1 / 54 (1.85%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Hangover			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Seasonal allergy			
subjects affected / exposed	1 / 57 (1.75%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	2	0	0
Social circumstances			
Sexual abuse			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Physical assault			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 57 (0.00%)	2 / 54 (3.70%)	1 / 42 (2.38%)
occurrences (all)	0	2	1
Vaginal haemorrhage			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	4 / 42 (9.52%)
occurrences (all)	0	0	4
Cough			
subjects affected / exposed	2 / 57 (3.51%)	1 / 54 (1.85%)	1 / 42 (2.38%)
occurrences (all)	2	1	1

Oropharyngeal pain			
subjects affected / exposed	3 / 57 (5.26%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	3	0	0
Nasal congestion			
subjects affected / exposed	2 / 57 (3.51%)	1 / 54 (1.85%)	0 / 42 (0.00%)
occurrences (all)	2	1	0
Rhinorrhoea			
subjects affected / exposed	1 / 57 (1.75%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Dry throat			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Psychiatric disorders			
Depressed mood			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 57 (1.75%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 57 (1.75%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Limb injury			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Tendon injury			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Wrist fracture			
subjects affected / exposed	1 / 57 (1.75%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			

subjects affected / exposed	7 / 57 (12.28%)	3 / 54 (5.56%)	2 / 42 (4.76%)
occurrences (all)	8	3	2
Presyncope			
subjects affected / exposed	2 / 57 (3.51%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	2	0	1
Dizziness			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Eye swelling			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Toothache			

subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	2
Rash			
subjects affected / exposed	1 / 57 (1.75%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Pseudofolliculitis barbae			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Acne			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 57 (1.75%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Arthralgia			
subjects affected / exposed	1 / 57 (1.75%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	1 / 57 (1.75%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Neck mass			

subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	5 / 57 (8.77%)	5 / 54 (9.26%)	1 / 42 (2.38%)
occurrences (all)	6	5	1
Chlamydial infection			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	1 / 57 (1.75%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	1 / 57 (1.75%)	1 / 54 (1.85%)	0 / 42 (0.00%)
occurrences (all)	1	1	0
Rhinitis			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0

Sinusitis			
subjects affected / exposed	0 / 57 (0.00%)	0 / 54 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo - Virus challenge phase	FP-01.1 - Follow-up	Placebo - Follow-up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 41 (39.02%)	9 / 57 (15.79%)	10 / 54 (18.52%)
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 41 (2.44%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	1	0	0
Hangover			
subjects affected / exposed	1 / 41 (2.44%)	0 / 57 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	1
Social circumstances			
Sexual abuse			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Physical assault			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			

Dysmenorrhoea			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 41 (0.00%)	1 / 57 (1.75%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	3 / 41 (7.32%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	5	0	0
Cough			
subjects affected / exposed	1 / 41 (2.44%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	2
Nasal congestion			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 41 (0.00%)	1 / 57 (1.75%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
Dry throat			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depressed mood			
subjects affected / exposed	1 / 41 (2.44%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	1	0	0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 41 (0.00%)	1 / 57 (1.75%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Tendon injury			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 41 (12.20%)	3 / 57 (5.26%)	1 / 54 (1.85%)
occurrences (all)	5	5	2
Presyncope			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 41 (2.44%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	1
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 57 (1.75%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
Eye pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 41 (0.00%)	1 / 57 (1.75%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
Vision blurred			

subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 41 (0.00%)	1 / 57 (1.75%)	0 / 54 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	1 / 41 (2.44%)	1 / 57 (1.75%)	0 / 54 (0.00%)
occurrences (all)	1	1	0
Dyspepsia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 41 (2.44%)	1 / 57 (1.75%)	0 / 54 (0.00%)
occurrences (all)	1	1	0
Vomiting			
subjects affected / exposed	1 / 41 (2.44%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 41 (2.44%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	1	0	0
Pseudofolliculitis barbae			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Acne			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	1
Arthralgia			

subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	2 / 41 (4.88%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	2	0	0
Myalgia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 41 (2.44%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	1	0	0
Neck mass			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	1
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	1 / 41 (2.44%)	3 / 57 (5.26%)	2 / 54 (3.70%)
occurrences (all)	1	3	3
Chlamydial infection			
subjects affected / exposed	1 / 41 (2.44%)	1 / 57 (1.75%)	0 / 54 (0.00%)
occurrences (all)	1	1	0
Conjunctivitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

Rhinitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	1 / 41 (2.44%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	1	0	0
Localised infection			
subjects affected / exposed	1 / 41 (2.44%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 57 (0.00%)	1 / 54 (1.85%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 57 (0.00%)	0 / 54 (0.00%)
occurrences (all)	1	0	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