Clinical trial results:
Immunogenicity and Tolerability Study of FLUVAL AB Novo Suspension for Injection (trivalent, seasonal influenza vaccine, active ingredient content: 6 g HA/strain/0.5 ml) for Children and Adolescents

Summary

EudraCT number	2013-003449-40
Trial protocol	HU
Global end of trial date	09 December 2014

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 Correction of data set.
Summary attachment (see zip file)	2013-003449-40-FSR-Synopsis (FABNovo-H-16-FSR_synopsis.pdf)

Trial information

Trial identification

Sponsor protocol code	FABNovo-H-16

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	Fö utca 7., Pilisborosjenö, 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	25 February 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 December 2014
Global end of trial reached?	Yes
Global end of trial date	09 December 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Assessment immunogenicity and safety of Fluval AB Novo seasonal influenza vaccine with 3 x 6 µgHA active ingredient in two age groups (children and adolescents).

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	18 October 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)	60
Adolescents (12-17 years)	60
Adults (18-64 years)	0

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

healthy volunteers of full contractual capacity were planned to be enrolled in two age groups (3 to 11 years and 12 to 18 years) from both sexes

Pre-assignment

Screening details:

Performance of brief physical examination, including measurement of heart rate, axillary temperature, blood pressure, check of the heart, lungs, and axillary lymph nodes, etc.

Period 1

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

Arms

Arm title	Treatment

Arm description:

Children 3-11 years:
Sixty (60) healthy volunteers of full contractual capacity from both sexes were enrolled.
Treatment: 0.5 x 6 µgHA/strain/0.5ml of Fluval AB Novo trivalent influenza vaccine was administered once at Day 0.

Adolescents 12-18 years:
Sixty (60) healthy volunteers of full contractual capacity from both sexes were enrolled.
Treatment: 1 x 6 µgHA/strain/0.5ml of Fluval AB Novo trivalent influenza vaccine was administered once at Day 0.

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

Dosage and administration details:

Children 3-11 years:
Treatment: 0.5 x 6 µgHA/strain/0.5ml of Fluval AB Novo trivalent influenza vaccine was administered once at Day 0.

Adolescents 12-18 years:
Treatment: 1 x 6 µgHA/strain/0.5ml of Fluval AB Novo trivalent influenza vaccine was administered once at Day 0.

Number of subjects in period 1	Treatment
Started	120
Completed	120

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description:

All one hundred and twenty (120) subjects entered in the study and were vaccinated (ITT population).

All one hundred and twenty (120) subjects attended visit at Day 21-28, all of whom (one hundred and twenty (120) subjects) data were available and evaluated (PP population).

Reporting group values	Overall trial	Total	
Number of subjects	120	120	
Age categorical			
Children 3-11 years: A child is belonging to age group 3-11 years, if he/she has already been turning 3 but has not yet been turning 12 on the day of vaccination. Adolescents 12-18 years: An adolescent subject is belonging to age group 12-18 years, if he/she has already been turning 12 but has not yet been turning 18 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)	60	60	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Children 3-11 years	60	60	
Age continuous			
Units: years			
median	11		
full range (min-max)	3 to 17	-	
Gender categorical			
Units: Subjects			
Female	53	53	
Male	67	67	

End points

End points reporting groups

Reporting group title	Treatment

Reporting group description:

Children 3-11 years:
Sixty (60) healthy volunteers of full contractual capacity from both sexes were enrolled.
Treatment: 0.5 x 6 µgHA/strain/0.5ml of Fluval AB Novo trivalent influenza vaccine was administered once at Day 0.

Adolescents 12-18 years:
Sixty (60) healthy volunteers of full contractual capacity from both sexes were enrolled.
Treatment: 1 x 6 µgHA/strain/0.5ml of Fluval AB Novo trivalent influenza vaccine was administered once at Day 0.

Primary: Geometric Mean Titers (GMTs) of influenza Antibodies Before and After Vaccination in subjects aged 3-11 years

End point title	Geometric Mean Titers (GMTs) of influenza Antibodies Before and After Vaccination in subjects aged 3-11 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			
Subject group type	Reporting group			
Number of subjects analysed	60[2]			
Units: Titers (1/dil)				
geometric mean (confidence interval 95%)				
A/H1N1; Day 0	31.8 (23.69 to 41.58)			
A/H1N1; Day 21	136.1 (106 to 174.8)			
A/H3N2; Day 0	92.96 (65.88 to 131.2)			
A/H3N2; Day 21	463.1 (349.8 to 613.2)			
B/; Day 0	17.82 (12.5 to 25.39)			
B/; Day 21	75.95 (51.64 to 111.7)			

Notes:

[2] - PP population in Children aged 3-11 years: sixty (60) persons.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Aged 3-11 years With Seroconversion Against Influenza Antigens Before and After Vaccination

End point title	Percentage of Subjects Aged 3-11 years With Seroconversion Against Influenza Antigens Before and After Vaccination[3]

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 post-vaccination/Day 0 (pre-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			
Subject group type	Reporting group			
Number of subjects analysed	60[4]			
Units: Percentage of subjects				
number (not applicable)				
A/H1N1; Day 21	61.67			
A/H3N2; Day 21	58.33			
B/; Day 21	66.67			

Notes:

[4] - PP population in Children aged 3-11 years: sixty (60) persons.

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers (GMTs) of Influenza Antibodies Before and After Vaccination with Fluval AB Novo in subjects 12-17 years.

End point title	Geometric Mean Titers (GMTs) of Influenza Antibodies Before and After Vaccination with Fluval AB Novo in subjects 12-17 years.[5]

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 post-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			
Subject group type	Reporting group			
Number of subjects analysed	60[6]			
Units: 1/dil				
geometric mean (confidence interval 95%)				
A/H1N1; Day 0	35.64 (26.06 to 48.74)			
A/H1N1; Day 21	167.6 (134 to 209.5)			
A/H3N2; Day 0	69.64 (46.4 to 104.5)			
A/H3N2; Day 21	417.4 (317.3 to 549)			
B/; Day 0	20.47 (15.24 to 27.49)			
B/; Day 21	97.36 (75.4 to 125.7)			

Notes:

[6] - PP population in Children aged 12-17 years: sixty (60) persons.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Aged 12 - 17 years With Seroconversion Against Influenza Antigens Before and After Vaccination

End point title	Percentage of Subjects Aged 12 - 17 years With Seroconversion Against Influenza Antigens Before and After 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. Seroprotection was defined as antibody titers ≥ 40 (1/dil).

End point type	Primary

End point timeframe:

Day 21 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			
Subject group type	Reporting group			
Number of subjects analysed	60[8]			
Units: Percentage of subjects				
number (not applicable)				
A/H1N1; Day 21	66.67			
A/H3N2; Day 21	61.67			
B/; Day 21	70			

Notes:

[8] - PP population in Children aged 12-17 years: sixty (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 3-11 years

End point title	Geometric Mean Titer Ratios (GMTRs) of influenza Antibodies After Vaccination in subjects aged 3-11 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			
Subject group type	Reporting group			
Number of subjects analysed	60[10]			
Units: Titer ratios (1/dil)				
geometric mean (confidence interval 95%)				
A/H1N1	4.337 (3.432 to 5.48)			
A/H3N2	4.982 (3.847 to 6.451)			
B/	4.262 (3.383 to 5.37)			

Notes:

[10] - PP population in Children aged 3-11 years: sixty (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 12-17 years

End point title	Geometric Mean Titer Ratios (GMTRs) of influenza Antibodies After Vaccination in subjects aged 12-17 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			
Subject group type	Reporting group			
Number of subjects analysed	60[12]			
Units: Titer ratios (1/dil)				
geometric mean (confidence interval 95%)				
A/H1N1	4.702 (3.595 to 6.151)			
A/H3N2	5.993 (4.207 to 8.539)			
B/	4.757 (3.762 to 6.014)			

Notes:

[12] - PP population in Children aged 12-17 years: sixty (60) persons.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Aged 3 to 11 Years With Seroprotection Against Influenza Antigens Before and After Vaccination

End point title	Percentage of Subjects Aged 3 to 11 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) and Day 21 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			
Subject group type	Reporting group			
Number of subjects analysed	60[14]			
Units: Percentage of subjects				
number (not applicable)				
A/H1N1; Day 0	50			
A/H1N1; Day 21	91.67			
A/H3N2; Day 0	70			
A/H3N2; Day 21	95			
B/; Day 0	26.67			
B/; Day 21	80			

Notes:

[14] - PP population in Children aged 3-11 years: sixty (60) persons.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Aged 12-17 Years With Seroprotection Against Influenza Antigens Before and After Vaccination

End point title	Percentage of Subjects Aged 12-17 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 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			
Subject group type	Reporting group			
Number of subjects analysed	60[16]			
Units: Percentage of subjects				
number (not applicable)				
A/H1N1; Day 0	56.67			
A/H1N1; Day 21	96.67			
A/H3N2; Day 0	58.33			
A/H3N2; Day 21	95			
B/; Day 0	40			
B/; Day 21	86.67			

Notes:

[16] - PP population in Children aged 12-17 years: sixty (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 3-11 years

End point title	Proportion of subjects seroconverted or had a significant increase in titres in subjects aged 3-11 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 to Day 21-28

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			
Subject group type	Reporting group			
Number of subjects analysed	60[18]			
Units: Percentage of subjects				
number (not applicable)				
A/H1N1	61.67			
A/H3N2	58.33			
B/	66.67			

Notes:

[18] - PP population in Children aged 3-11 years: sixty (60) persons.

Statistical analyses

No statistical analyses for this end point

Primary: Increase in GMT in subjects aged 3-11 years

End point title	Increase in GMT in subjects aged 3-11 years[19]

End point description:

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

End point type	Primary

End point timeframe:

Day 0 to Day 21-28

Notes:

[19] - 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			
Subject group type	Reporting group			
Number of subjects analysed	60[20]			
Units: unit(s)				
number (not applicable)				
A/H1N1	4.337			
A/H3N2	4.982			
B/	4.262			

Notes:

[20] - PP population in Children aged 3-11 years: sixty (60) persons.

Statistical analyses

No statistical analyses for this end point

Primary: Proportion of subjects seroprotected in subjects aged 3-11 years

End point title	Proportion of subjects seroprotected in subjects aged 3-11 years[21]

End point description:

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

End point type	Primary

End point timeframe:

Day 0 to Day 21-28.

Notes:

[21] - 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			
Subject group type	Reporting group			
Number of subjects analysed	60[22]			
Units: Percentage of subjects				
number (not applicable)				
A/H1N1	91.67			
A/H3N2	95			
B/	80			

Notes:

[22] - PP population in Children aged 3-11 years: sixty (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 12-17 years

End point title	Proportion of subjects seroconverted or had a significant increase in titres in subjects aged 12-17 years[23]

End point description:

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

End point type	Primary

End point timeframe:

Day 0 to Day21-28.

Notes:

[23] - 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			
Subject group type	Reporting group			
Number of subjects analysed	60[24]			
Units: Percentage of subjects				
number (not applicable)				
A/H1N1	66.67			
A/H3N2	61.67			
B/	70			

Notes:

[24] - PP population in Children aged 12-17 years: sixty (60) persons.

Statistical analyses

No statistical analyses for this end point

Primary: Increase in GMT in subjects aged 12-17 years

End point title	Increase in GMT in subjects aged 12-17 years[25]

End point description:

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

End point type	Primary

End point timeframe:

Day 0 to day 21-28.

Notes:

[25] - 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			
Subject group type	Reporting group			
Number of subjects analysed	60[26]			
Units: unit(s)				
number (not applicable)				
A/H1N1	4.702			
A/H3N2	5.993			
B/	4.757			

Notes:

[26] - PP population in Children aged 12-17 years: sixty (60) persons.

Statistical analyses

No statistical analyses for this end point

Primary: Proportion of subjects seroprotected in subjects aged 12-17 years

End point title	Proportion of subjects seroprotected in subjects aged 12-17 years[27]

End point description:

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

End point type	Primary

End point timeframe:

Day 0 to day 21-28.

Notes:

[27] - 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			
Subject group type	Reporting group			
Number of subjects analysed	60[28]			
Units: Percentage of subjects				
number (not applicable)				
A/H1N1	96.67			
A/H3N2	95			
B/	86.67			

Notes:

[28] - PP population in Children aged 12-17 years: sixty (60) persons.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Day 0 to day 21-28.	
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	50 / 120 (41.67%)		
Nervous system disorders			
Headache	Additional description: 1 of them was not related to the study medication, according to the investigator.		
subjects affected / exposed	5 / 120 (4.17%)		
occurrences (all)	5		
Syncope	Additional description: All of them was not related to the study medication, according to the investigator.		
subjects affected / exposed	3 / 120 (2.50%)		
occurrences (all)	3		
General disorders and administration site conditions			
Vaccination site pain			
subjects affected / exposed	38 / 120 (31.67%)		
occurrences (all)	38		
Vaccination site erythema			

subjects affected / exposed	9 / 120 (7.50%)		
occurrences (all)	9		
Vaccination site induration			
subjects affected / exposed	8 / 120 (6.67%)		
occurrences (all)	8		
Vaccination site swelling			
subjects affected / exposed	9 / 120 (7.50%)		
occurrences (all)	9		
Vaccination site haematoma			
subjects affected / exposed	2 / 120 (1.67%)		
occurrences (all)	2		
Chills	Additional description: 2 of them were not related to the study medication, according to the investigator.		
subjects affected / exposed	3 / 120 (2.50%)		
occurrences (all)	3		
Malaise	Additional description: 1 of them was not related to the study medication, according to the investigator.		
subjects affected / exposed	9 / 120 (7.50%)		
occurrences (all)	9		
Pyrexia	Additional description: 3 of them were not related to the study medication, according to the investigator.		
subjects affected / exposed	6 / 120 (5.00%)		
occurrences (all)	6		
Immune system disorders			
Hypersensitivity	Additional description: All of them was not related to the study medication, according to the investigator.		
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Gastrointestinal disorders			
Vomiting	Additional description: 1 of them was not related to the study medication, according to the investigator.		
subjects affected / exposed	2 / 120 (1.67%)		
occurrences (all)	2		
Abdominal pain			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain	Additional description: All of them was not related to the study medication, according to the investigator.		

subjects affected / exposed	2 / 120 (1.67%)		
occurrences (all)	2		
Cough	Additional description: All of them was not related to the study medication, according to the investigator.		
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	12 / 120 (10.00%)		
occurrences (all)	12		
Infections and infestations			
Nasopharyngitis	Additional description: All of them was not related to the study medication, according to the investigator.		
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Pharyngitis	Additional description: All of them was not related to the study medication, according to the investigator.		
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Cystitis	Additional description: All of them was not related to the study medication, according to the investigator.		
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Helminthic infection	Additional description: All of them was not related to the study medication, according to the investigator.		
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