Clinical trial results:
A multicenter, randomized, double-blind, placebo-controlled phase III study to evaluate the efficacy and safety of omalizumab in patients with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine therapy

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com/CtrdWeb/home.novfor complete trial results.

Summary

EudraCT number	2016-002273-35
Trial protocol	Outside EU/EEA
Global end of trial date	03 December 2015

Results information

Result version number	v1 (current)
This version publication date	11 July 2018
First version publication date	11 July 2018

Trial information

Trial identification

Sponsor protocol code	CIGE025E2306

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02329223
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111,
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111,

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	Yes

1901/2006 apply to this trial?	

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	03 December 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 December 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to demonstrate the superiority of omalizumab 300 mg and / or 150 mg injected subcutaneously every 4 weeks in patients with refractory CSU receiving concomitant H1 antihistamine (H1AH) therapy with respect to a reduction from baseline in the weekly itch severity score at Week 12, compared to placebo.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 December 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	Japan: 105
Country: Number of subjects enrolled	Korea, Republic of: 113
Worldwide total number of subjects	218
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	1
Adolescents (12-17 years)	3
Adults (18-64 years)	202
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants were randomly assigned to the 3 treatment groups in a 1:1:1 ratio.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Omalizumab 300 mg

Arm description:

Participants received omalizumab 300 mg subcutaneously every 4 weeks during the 12 week treatment period.

Arm type	Experimental
Investigational medicinal product name	Omalizumab
Investigational medicinal product code	IGE025
Other name	Xolair
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received omalizumab 300 mg subcutaneously every 4 weeks during the 12 week treatment period.

Arm title	Omalizumab 150 mg

Arm description:

Participants received omalizumab 150 mg subcutaneously every 4 weeks during the 12 week treatment period.

Arm type	Experimental
Investigational medicinal product name	Omalizumab
Investigational medicinal product code	IGE025
Other name	Xolair
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received omalizumab 150 mg subcutaneously every 4 weeks during the 12 week treatment period.

Arm title	Placebo

Arm description:

Participants will receive placebo subcutaneously every 4 weeks during the 12 week treatment period.

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received placebo subcutaneously every 4 weeks during the 12 week treatment period.

Number of subjects in period 1	Omalizumab 300 mg	Omalizumab 150 mg	Placebo
Started	73	71	74
Full Analysis Set	73	70	74
Safety Set	73	71	74
Completed	72	68	68
Not completed	1	3	6
Consent withdrawn by subject	1	2	5
Physician decision	-	-	1
Adverse event, non-fatal	-	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Omalizumab 300 mg
Reporting group description:	
Participants received omalizumab 300 mg subcutaneously every 4 weeks during the 12 week treatment period.	
Reporting group title	Omalizumab 150 mg
Reporting group description:	
Participants received omalizumab 150 mg subcutaneously every 4 weeks during the 12 week treatment period.	
Reporting group title	Placebo
Reporting group description:	
Participants will receive placebo subcutaneously every 4 weeks during the 12 week treatment period.	

Reporting group values	Omalizumab 300 mg	Omalizumab 150 mg	Placebo
Number of subjects	73	71	74
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	1	0
Adolescents (12-17 years)	2	0	1
Adults (18-64 years)	66	69	67
From 65-84 years	5	1	6
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	44.6	43.6	42.5
standard deviation	± 14.86	± 12.24	± 14.26
Gender, Male/Female Units: Participants			
Female	40	43	48
Male	33	28	26

Reporting group values	Total		
Number of subjects	218		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	1		
Adolescents (12-17 years)	3		

Adults (18-64 years)	202		
From 65-84 years	12		
85 years and over	0		
Age Continuous Units: Years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female Units: Participants			
Female	131		
Male	87		

End points

End points reporting groups

Reporting group title	Omalizumab 300 mg
Reporting group description:	
Participants received omalizumab 300 mg subcutaneously every 4 weeks during the 12 week treatment period.	
Reporting group title	Omalizumab 150 mg
Reporting group description:	
Participants received omalizumab 150 mg subcutaneously every 4 weeks during the 12 week treatment period.	
Reporting group title	Placebo
Reporting group description:	
Participants will receive placebo subcutaneously every 4 weeks during the 12 week treatment period.	

Primary: Change From Baseline (BL) in Weekly Itch Severity Score at Week 12

End point title	Change From Baseline (BL) in Weekly Itch Severity Score at Week 12
End point description:	
The weekly itch severity score is a component of the Urticaria Activity Score 7 (UAS7) composite score. The UAS7 is a composite score of the number of wheals (hives) and the severity of the itch. The weekly itch severity score is the sum of the daily itch severity scores over 7 days and ranges from 0 to 21. The daily itch severity score is the average of the morning and evening scores on a scale of 0 (none) to 3 (severe). The Baseline weekly itch severity score is the sum of the daily itch severity scores over the 7 days prior to the first treatment. A higher itch severity score indicates more severe itching. A negative change score from baseline indicates improvement.	
End point type	Primary
End point timeframe:	
Baseline to Week 12	

End point values	Omalizumab 300 mg	Omalizumab 150 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	73	70	74	
Units: Units on a scale				
least squares mean (standard error)	-10.22 (± 0.571)	-8.8 (± 0.591)	-6.51 (± 0.581)	

Statistical analyses

Statistical analysis title	Change from BL in weekly itch severity score
Comparison groups	Omalizumab 300 mg v Placebo

Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Mixed Models with repeated measures
Parameter estimate	Mean difference (net)
Point estimate	-3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.31
upper limit	-2.098
Variability estimate	Standard error of the mean
Dispersion value	0.815

Statistical analysis title	Change from BL in weekly itch severity score
Comparison groups	Omalizumab 150 mg v Placebo
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006
Method	Mixed Model with repeated measure(MMRM)
Parameter estimate	Mean difference (net)
Point estimate	-2.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.921
upper limit	-0.654
Variability estimate	Standard error of the mean
Dispersion value	0.828

Secondary: Change From Baseline in the Urticaria Activity Score Over 7 Days (UAS7) at Week 12

End point title	Change From Baseline in the Urticaria Activity Score Over 7 Days (UAS7) at Week 12

End point description:

The UAS7 is a composite score of the number of wheals (hives) and the severity of the itch. The UAS7 is determined by the sum of the daily urticaria activity scores over 7 days and ranges from 0 to 42. The daily urticaria activity score is the average of the morning and evening urticaria activity scores and ranges from 0 to 6. The urticaria activity score is the sum of ratings on a scale of 0 to 3 (0=none to 3=intense/severe) for (1) the number of wheals (hives) and (2) itch intensity over the previous 12 hours, ranges from 0 to 6, and is measured twice daily (morning and evening). The Baseline score is the sum of the daily urticaria activity scores over the 7 days prior to the first treatment. A higher urticaria activity score indicates more severe symptoms. A negative change score from baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline to Week 12

End point values	Omalizumab 300 mg	Omalizumab 150 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	73	70	74	
Units: Units on a scale				
least squares mean (standard error)	-22.44 (± 1.243)	-18.79 (± 1.288)	-13.9 (± 1.265)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Weekly Number of Hives Score at Week 12

End point title	Change From Baseline in the Weekly Number of Hives Score at Week 12

End point description:

The weekly hives score is the sum of the daily hives scores over 7 days and ranges from 0 to 21. The number of hives is measured twice daily (morning and evening) on a scale of 0 (none) to 3 (> 12 hives per 12 hours). The daily hives score is the average of the morning and evening scores. The Baseline score is the sum of the daily hives scores over the 7 days prior to the first treatment. A higher score indicates more hives. A negative change score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline to Week 12

End point values	Omalizumab 300 mg	Omalizumab 150 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	73	70	74	
Units: Units on a scale				
least squares mean (standard error)	-12.17 (± 0.742)	-10.04 (± 0.769)	-7.41 (± 0.756)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a UAS7 Score ≤ 6 at Week 12

End point title	Percentage of Participants With a UAS7 Score ≤ 6 at Week 12

End point description:

The UAS7 is a composite score of the number of wheals (hives) and the severity of the itch. The UAS7 is determined by the sum of the daily urticaria activity scores over 7 days and ranges from 0 to 42. The daily urticaria activity score is the average of the morning and evening urticaria activity scores and ranges from 0 to 6. The urticaria activity score is the sum of ratings on a scale of 0 to 3 (0=none to

3=intense/severe) for (1) the number of wheals (hives) and (2) itch intensity over the previous 12 hours, ranges from 0 to 6, and is measured twice daily (morning and evening). The Baseline score is the sum of the daily urticaria activity scores over the 7 days prior to the first treatment. A higher urticaria activity score indicates more severe symptoms.

End point type	Secondary

End point timeframe:

Week 12

End point values	Omalizumab 300 mg	Omalizumab 150 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	73	70	74	
Units: Percentage of participants				
number (not applicable)	57.5	42.9	18.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Weekly Size of the Largest Hive Score at Week 12

End point title	Change From Baseline in the Weekly Size of the Largest Hive Score at Week 12

End point description:

The weekly size of the largest hive score is the sum of the daily size of the largest hive scores over 7 days and ranges from 0 to 21. The daily size of the largest hive score is assessed twice daily (morning and evening) on a scale of 0 (none) to 3 (> 2.5 cm). The daily size of the largest hive score is the average of the morning and evening scores. The Baseline weekly size of the largest hive score is calculated over the 7 days prior to the first treatment. A higher score indicates larger hives. A negative change score from baseline indicates a reduction in hive size.

End point type	Secondary

End point timeframe:

Baseline to Week 12

End point values	Omalizumab 300 mg	Omalizumab 150 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	73	70	74	
Units: Units on a scale				
least squares mean (standard error)	-10.71 (± 0.684)	-9.3 (± 0.709)	-6.27 (± 0.696)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Weekly Itch Severity Score Minimally Important Difference (MID) Responders at Week 12

End point title	Percentage of Weekly Itch Severity Score Minimally Important Difference (MID) Responders at Week 12

End point description:

Weekly itch severity score MID response is defined as a reduction from baseline in AUS7 of >=5 points.

End point type	Secondary

End point timeframe:

Week 12

End point values	Omalizumab 300 mg	Omalizumab 150 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	73	70	74	
Units: Percentage of participants				
number (not applicable)	87.7	68.6	55.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Complete Responders (UAS7 = 0) at Week 12

End point title	Percentage of Complete Responders (UAS7 = 0) at Week 12

End point description:

Complete responders are defined as participants who achieved AUS7 = 0.

End point type	Secondary

End point timeframe:

Week 12

End point values	Omalizumab 300 mg	Omalizumab 150 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	73	70	74	
Units: Percentage of participants				
number (not applicable)	35.6	18.6	4.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Overall Dermatology Life Quality Index (DLQI) Score at Week 12

End point title	Change From Baseline in the Overall Dermatology Life Quality Index (DLQI) Score at Week 12

End point description:

The DLQI is a 10-item dermatology-specific health-related quality of life measure. Participants rated their dermatology symptoms as well as the impact of their skin condition on various aspects of their lives on a scale of 0 (Not at all) to 3 (Very much). The overall DLQI is the sum of the responses to the 10 items and ranges from 0 to 30. A lower score indicates a better quality of life. A negative change score from baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline to Week 12

End point values	Omalizumab 300 mg	Omalizumab 150 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	71	69	74	
Units: Units on a scale				
least squares mean (standard error)	-8.4 (± 0.52)	-7.2 (± 0.53)	-5.3 (± 0.52)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with production of anti-omalizumab antibody

End point title	Percentage of Participants with production of anti-omalizumab antibody[1]

End point description:

Serum samples were collected for anti-omalizumab antibody testing.

End point type	Secondary

End point timeframe:

Week 24

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The placebo group does not apply to this end point.

End point values	Omalizumab 300 mg	Omalizumab 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	68	64		
Units: Percentage of participants				
number (not applicable)				
Conclusive results (n=64,63) Inconclusive results (n=4,1)	0 9999	0 9999		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All adverse events reported in this record are from date of First Patient First Treatment until Last Patient Last Visit.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

Reporting groups

Reporting group title	IGE025 300 mg
Reporting group description: IGE025 300 mg	
Reporting group title	IGE025 150 mg
Reporting group description: IGE025 150 mg	
Reporting group title	Placebo
Reporting group description: Placebo	

Serious adverse events	IGE025 300 mg	IGE025 150 mg	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 73 (4.11%)	3 / 71 (4.23%)	0 / 74 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
LIMB TRAUMATIC AMPUTATION			
subjects affected / exposed	0 / 73 (0.00%)	1 / 71 (1.41%)	0 / 74 (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
SPINAL CORD INJURY			
subjects affected / exposed	0 / 73 (0.00%)	1 / 71 (1.41%)	0 / 74 (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
Hepatobiliary disorders			
CHOLECYSTITIS CHRONIC			

subjects affected / exposed	1 / 73 (1.37%)	0 / 71 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ASTHMA			
subjects affected / exposed	0 / 73 (0.00%)	1 / 71 (1.41%)	0 / 74 (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			
PNEUMONIA			
subjects affected / exposed	1 / 73 (1.37%)	1 / 71 (1.41%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DIABETES MELLITUS			
subjects affected / exposed	1 / 73 (1.37%)	0 / 71 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	IGE025 300 mg	IGE025 150 mg	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	32 / 73 (43.84%)	25 / 71 (35.21%)	29 / 74 (39.19%)
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	2 / 73 (2.74%)	1 / 71 (1.41%)	0 / 74 (0.00%)
occurrences (all)	2	1	0
Nervous system disorders			
HEADACHE			
subjects affected / exposed	3 / 73 (4.11%)	3 / 71 (4.23%)	5 / 74 (6.76%)
occurrences (all)	7	3	6
MIGRAINE			
subjects affected / exposed	2 / 73 (2.74%)	0 / 71 (0.00%)	0 / 74 (0.00%)
occurrences (all)	4	0	0
SOMNOLENCE			

subjects affected / exposed	2 / 73 (2.74%)	0 / 71 (0.00%)	1 / 74 (1.35%)
occurrences (all)	2	0	1
Gastrointestinal disorders			
CONSTIPATION			
subjects affected / exposed	0 / 73 (0.00%)	2 / 71 (2.82%)	0 / 74 (0.00%)
occurrences (all)	0	2	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 73 (0.00%)	2 / 71 (2.82%)	0 / 74 (0.00%)
occurrences (all)	0	2	0
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	2 / 73 (2.74%)	0 / 71 (0.00%)	0 / 74 (0.00%)
occurrences (all)	2	0	0
CHRONIC SPONTANEOUS URTICARIA			
subjects affected / exposed	3 / 73 (4.11%)	1 / 71 (1.41%)	1 / 74 (1.35%)
occurrences (all)	3	1	1
DERMATITIS CONTACT			
subjects affected / exposed	1 / 73 (1.37%)	0 / 71 (0.00%)	3 / 74 (4.05%)
occurrences (all)	1	0	4
ECZEMA			
subjects affected / exposed	5 / 73 (6.85%)	3 / 71 (4.23%)	2 / 74 (2.70%)
occurrences (all)	5	3	3
MILIARIA			
subjects affected / exposed	2 / 73 (2.74%)	1 / 71 (1.41%)	1 / 74 (1.35%)
occurrences (all)	2	1	1
URTICARIA			
subjects affected / exposed	2 / 73 (2.74%)	4 / 71 (5.63%)	2 / 74 (2.70%)
occurrences (all)	2	5	2
Psychiatric disorders			
INSOMNIA			
subjects affected / exposed	0 / 73 (0.00%)	0 / 71 (0.00%)	2 / 74 (2.70%)
occurrences (all)	0	0	2
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	2 / 73 (2.74%)	0 / 71 (0.00%)	0 / 74 (0.00%)
occurrences (all)	2	0	0

Infections and infestations			
BRONCHITIS			
subjects affected / exposed	2 / 73 (2.74%)	0 / 71 (0.00%)	0 / 74 (0.00%)
occurrences (all)	2	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 73 (0.00%)	1 / 71 (1.41%)	2 / 74 (2.70%)
occurrences (all)	0	1	2
CYSTITIS			
subjects affected / exposed	0 / 73 (0.00%)	2 / 71 (2.82%)	0 / 74 (0.00%)
occurrences (all)	0	2	0
FOLLICULITIS			
subjects affected / exposed	1 / 73 (1.37%)	2 / 71 (2.82%)	0 / 74 (0.00%)
occurrences (all)	1	2	0
NASOPHARYNGITIS			
subjects affected / exposed	9 / 73 (12.33%)	7 / 71 (9.86%)	12 / 74 (16.22%)
occurrences (all)	10	10	14
OTITIS EXTERNA			
subjects affected / exposed	0 / 73 (0.00%)	0 / 71 (0.00%)	2 / 74 (2.70%)
occurrences (all)	0	0	2
PHARYNGITIS			
subjects affected / exposed	3 / 73 (4.11%)	3 / 71 (4.23%)	0 / 74 (0.00%)
occurrences (all)	3	3	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 73 (0.00%)	3 / 71 (4.23%)	0 / 74 (0.00%)
occurrences (all)	0	3	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 October 2014	Amendment 1 (10-Oct-2014), issued before any patients had been enrolled, introduced the following changes to incorporate updated information elicited by dedicated study feasibility assessments and feedback from contracted vendors: Changed basophil high-affinity IgE receptor density assessment from mandatory to optional. Updated treatment assignment and randomization procedures. Updated logistics of dispensing the investigational treatment. Updated the list of permitted and prohibited concomitant medications. Updated site monitoring procedures as the central analysis was no longer applied in this study. Updated the blood log according to the vendor's instructions. Clearly defined UAS7 and weekly itch severity score in Glossary of terms.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com/CtrdWeb/home.novfor complete trial results.

Notes: