Clinical trial results:
A multicenter, randomized, double-blind, placebo-controlled 12-week, parallel-group study with a 6 week follow up period to demonstrate efficacy and safety of subcutaneous Omalizumab in patients with urticaria factitia refractory to standard treatment

Summary

EudraCT number	2011-005615-87
Trial protocol	DE
Global end of trial date	25 March 2015

Results information

Result version number	v1 (current)
This version publication date	16 September 2021
First version publication date	16 September 2021
Summary attachment (see zip file)	Symptomatic dermographism patients (04 Maurer et al Suppl Figure E1 UFO.pptx) Symptomatic dermographism patients (06 Maurer et al Suppl Table E2 UFO.docx) Publication (Maurer et al, JACI 2017.pdf)

Trial information

Trial identification

Sponsor protocol code	CIGE025EDE17T

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Allergie-Centrum-Charité, Charité - Universitätsmedizin Berlin
Sponsor organisation address	Charitéplatz 1, Berlin, Germany, 10117
Public contact	Hesna Gözlükaya, Allergie-Centrum-Charité, Charité - Universitätsmedizin Berlin, 49 30450518296, hesna.goezluekaya@charite.de
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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	01 December 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 March 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the effects of 150 and 300 mg omalizumab on wheal development in patients with urticaria factitia

Protection of trial subjects:

Omalizumab (Xolair®) is a recombinant humanized monoclonal antibody that binds to IgE at its binding site to FcεRI. Omalizumab is currently indicated in patients with moderate to severe allergic asthma, 12 years and older. Up to now, more than 100,000 patients have been treated with omalizumab worldwide. Free IgE levels fall between 89-98% over 16 to 24 weeks of therapy. Associated with the fall in free IgE levels is a down-regulation in the expression of FcεRI receptors on basophils and mast cells. This mechanism of action is postulated to account for the reduction of exacerbations and symptoms of allergic asthma. In the EU, omalizumab is licensed for severe allergic asthma, while there is an expanded indication to moderate allergic asthma in the USA.

Safety parameters were documented at each study visit and reported accordingly. Safety parameters included adverse events, laboratory values, clinical monitoring, and prescribed clinic visits.
There were no significant differences in the frequency of occurrence of adverse events or other unexpected events between the omalizumab groups and the placebo group.

Background therapy:

No backround therapy

Evidence for comparator: -

Actual start date of recruitment	02 July 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 61
Worldwide total number of subjects	61
EEA total number of subjects	61

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)	50
From 65 to 84 years	11
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 3 study centers in Germany, between December 2012 (first patient first visit) and December 2014 (last patient last visit).

Pre-assignment

Screening details:

60 patients with chronic urticaria factitia were planned, 61 were randomized, all 61 were analyzed regarding safety and 55 regarding efficacy.

A total of 61 subjects entered the screening period (up to 2 weeks). All 61 subjects were randomized and received at least (two) dose of study drug.

Pre-assignment period milestones

Number of subjects started	61
Number of subjects completed	61

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	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Omalizumab 150mg

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Omalizumab 150mg
Investigational medicinal product code	
Other name	Xolair
Pharmaceutical forms	Suspension for emulsion for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Drug: Omalizumab

150mg, s.c., every 4 weeks

Arm title	Omalizumab 300mg

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Omalizumab
Investigational medicinal product code	
Other name	Xolair
Pharmaceutical forms	Suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Omalizumab

150mg, s.c., every 4 weeks

Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Drug: Placebo

Placebo, s.c., every 4 weeks

Number of subjects in period 1	Omalizumab 150mg	Omalizumab 300mg	Placebo
Started	19	21	21
Completed	19	21	21

Baseline characteristics

Reporting groups	
Reporting group title	Omalizumab 150mg
Reporting group description: -	
Reporting group title	Omalizumab 300mg
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Reporting group values	Omalizumab 150mg	Omalizumab 300mg	Placebo
Number of subjects	19	21	21
Age categorical			
as described in the manuscript			
Units: Subjects			
Age 26-46 years	0	0	21
Age 34-52 years	19	0	0
Age 31-51 years	0	21	0
Gender categorical			
as described in the manuscript			
Units: Subjects			
Female	13	9	12
Male	6	12	9

Reporting group values	Total		
Number of subjects	61		
Age categorical			
as described in the manuscript			
Units: Subjects			
Age 26-46 years	21		
Age 34-52 years	19		
Age 31-51 years	21		
Gender categorical			
as described in the manuscript			
Units: Subjects			
Female	34		
Male	27		

End points

End points reporting groups

Reporting group title	Omalizumab 150mg
Reporting group description: -	
Reporting group title	Omalizumab 300mg
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: Change in Provocation Thresholds From Baseline to Day 70 in Urticaria Factitia Patients After Treatment With Omalizumab Compared to Placebo

End point title	Change in Provocation Thresholds From Baseline to Day 70 in Urticaria Factitia Patients After Treatment With Omalizumab Compared to Placebo[1]
End point description: every 4 weeks	
End point type	Primary
End point timeframe: 70 days	

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: See manuskript

End point values	Omalizumab 150mg	Omalizumab 300mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	21	21	
Units: wheal development up to four pins				
geometric mean (standard deviation)	-1.8 (± 1.7)	-2.0 (± 1.8)	-0.6 (± 1.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: To assess the effects of omalizumab in urticaria factitia patients on quality of life

End point title	To assess the effects of omalizumab in urticaria factitia patients on quality of life
End point description: every 4 weeks	
End point type	Secondary
End point timeframe: 70 days	

End point values	Omalizumab 150mg	Omalizumab 300mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	21	21	
Units: Dermatology quality of life score				
geometric mean (standard error)	-6.611 (± 1.234)	-5.579 (± 1.478)	-2.316 (± 0.949)	

Statistical analyses

No statistical analyses for this end point

Secondary: To assess the effects of omalizumab in UF patients on physician global assessment of disease severity

End point title	To assess the effects of omalizumab in UF patients on physician global assessment of disease severity
End point description: every 4 weeks	
End point type	Secondary
End point timeframe: 70 days	

End point values	Omalizumab 150mg	Omalizumab 300mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	18	19	20[2]	
Units: units on a sclae				
geometric mean (standard error)	21.8 (± 3.63)	28.33 (± 6.23)	40.32 (± 6.162)	

Notes:

[2] - Data were not collected

Statistical analyses

No statistical analyses for this end point

Secondary: To assess long-term effects of omalizumab in UF patients, change in friction thresholds from day 70 (week 10) to day 112 (week 16) will be assessed

End point title	To assess long-term effects of omalizumab in UF patients, change in friction thresholds from day 70 (week 10) to day 112 (week 16) will be assessed
End point description: every 4 weeks	
End point type	Secondary

End point timeframe:
112 days

End point values	Omalizumab 150mg	Omalizumab 300mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	21	21	
Units: Fric Test grades				
geometric mean (standard deviation)	-1.0556 (± 1.39209)	-0.8421 (± 1.77210)	-0.8333 (± 1.50489)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Serious Adverse Events and Adverse Events

End point title	Number of Participants with Serious Adverse Events and Adverse Events
End point description: every 4 weeks	
End point type	Secondary
End point timeframe: 112	

End point values	Omalizumab 150mg	Omalizumab 300mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	21	21	
Units: participants				
number (not applicable)	1	1	1	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
During the whole trial	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	no dictionary used
Dictionary version	0

Reporting groups	
Reporting group title	Omalizumab 150mg
Reporting group description: -	
Reporting group title	Omalizumab 300mg
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	Omalizumab 150mg	Omalizumab 300mg	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 19 (5.26%)	1 / 21 (4.76%)	1 / 21 (4.76%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Surgical and medical procedures			
Inguinal hernia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 21 (0.00%)	0 / 21 (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
Renal and urinary disorders			
Unspecified renal colic			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Cystitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 21 (4.76%)	0 / 21 (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

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

Non-serious adverse events	Omalizumab 150mg	Omalizumab 300mg	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 19 (94.74%)	15 / 21 (71.43%)	18 / 21 (85.71%)
General disorders and administration site conditions			
Headache			
subjects affected / exposed	6 / 19 (31.58%)	9 / 21 (42.86%)	10 / 21 (47.62%)
occurrences (all)	6	9	10
Respiratory, thoracic and mediastinal disorders			
Upper respiratory tract infection			
subjects affected / exposed	12 / 19 (63.16%)	6 / 21 (28.57%)	8 / 21 (38.10%)
occurrences (all)	12	6	8

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