



Clinical trial results:

Effect of Omalizumab in patients with Aspirin-Exacerbated Respiratory Disease (AERD)

Summary

EudraCT number	2017-003119-21
Trial protocol	AT
Global end of trial date	31 January 2021

Results information

Result version number	v1 (current)
This version publication date	04 April 2026
First version publication date	04 April 2026

Trial information

Trial identification

Sponsor protocol code	1
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Waehringer Guertel 18-20, Vienna, Austria, 1090
Public contact	Univ.Prof. Dr. Georg Stingl, Medical University of Vienna, 0043 14040077050, georg.stingl@meduniwien.ac.at
Scientific contact	Univ.Prof. Dr. Georg Stingl, Medical University of Vienna, 0043 14040077050, georg.stingl@meduniwien.ac.at

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	31 January 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 January 2021
Global end of trial reached?	Yes
Global end of trial date	31 January 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To test the efficacy of omalizumab in patients with AERD regarding intolerance of salicylic acid after 6 months. This will be evaluated by oral drug provocation testing with low dose salicylic acid after 6 months of omalizumab Treatment.

Protection of trial subjects:

Following comprehensive instruction regarding the nature, significance, impact and risks of this clinical trial, the patient must have given written consent to participation in the study. During the instruction the trial participants were to be made aware of the fact that they can withdraw their consent – without giving reasons – at any time without their further medical care being influenced in any way.

In addition to the comprehensive instructions was given to the trial participants by the Investigator, the trial participants also receive a written patient information sheet in comprehensible language, explaining the nature and purpose of the study and its progress. The patients must have agreed to the possibility of study-related data being passed on to relevant authorities.

The patients must have been informed in detail of their obligations in relation to the trial participants insurance in order not to jeopardize insurance cover.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 October 2017
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	Austria: 33
Worldwide total number of subjects	33
EEA total number of subjects	33

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	33
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Before study initiation, informed consent was obtained from all subjects. All patients with AERD could have been included according to inclusion- and exclusion criteria. AERD patients who had already obtained omalizumab for the treatment of asthma were also included and evaluated retrospectively.

Pre-assignment

Screening details:

The first visit was performed at screening (day 0, V1/before omalizumab therapy). Clinically significant abnormal laboratory values and active infection (Tbc, HIV, hepatitis A/B/C) were ruled out prior to the first dose.

Period 1

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

Arms

Arm title	Omalizumab
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Arm description:

Xolair (Omalizumab)
Individual dosing according to IgE levels and body weight
Administered subcutaneous every 2-4 weeks

Arm type	Active comparator
Investigational medicinal product name	Omalizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Xolair (Omalizumab)
Individual dosing according to IgE levels and body weight
Administered subcutaneous every 2-4 weeks

Number of subjects in period 1	Omalizumab
Started	33
Completed	33

Baseline characteristics

End points

End points reporting groups

Reporting group title	Omalizumab
Reporting group description: Xolair (Omalizumab) Individual dosing according to IgE levels and body weight Administered subcutaneous every 2-4 weeks	
Subject analysis set title	Before Omalizumab
Subject analysis set type	Full analysis
Subject analysis set description: Patients before omalizumab therapy	
Subject analysis set title	after omalizumab
Subject analysis set type	Full analysis
Subject analysis set description: after 6 months of omalizumab	

Primary: Omalizumab Effect on aspirin tolerance in atopic and nonatopic N-ERD patients

End point title	Omalizumab Effect on aspirin tolerance in atopic and nonatopic N-ERD patients
End point description: As primary endpoint, the efficacy of omalizumab in patients with aspirin intolerance will be evaluated by oral exposure to low-dose acetylsalicylic acid before and after 6 months of treatment. At both timepoints, the dose of acetylsalicylic acid will be slowly increased until an intolerance reaction occurs or up to a maximum dose of 500mg and patients' symptoms will be documented.	
End point type	Primary
End point timeframe: 6 months	

End point values	Before Omalizumab	after omalizumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: number	33	33		

Statistical analyses

Statistical analysis title	Induction of aspirin tolerance after omalizumab tr
Comparison groups	Before Omalizumab v after omalizumab
Number of subjects included in analysis	66
Analysis specification	Post-hoc
Analysis type	other
P-value	< 0.5
Method	McNemar

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were recorded at each visit. There is no specific time frame.

Adverse event reporting additional description:

Only 7 patients (19%) reported adverse events during omalizumab treatment. Four patients developed headaches between weeks 4 and 24, which occurred a few hours after injection and usually resolved within 1 day. Joint pain was reported by 3 patients, but only 1 patient had to discontinue treatment at week 20 owing to severe discomfort.

Assessment type	Systematic
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Dictionary used

Dictionary name	visit protocoll
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Dictionary version	1.0
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Reporting groups

Reporting group title	adverse events
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Reporting group description: -

Serious adverse events	adverse events		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 33 (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	adverse events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 33 (21.21%)		
General disorders and administration site conditions			
headache			
subjects affected / exposed	4 / 33 (12.12%)		
occurrences (all)	4		
Musculoskeletal and connective tissue disorders			
joint pain			
subjects affected / exposed	3 / 33 (9.09%)		
occurrences (all)	3		

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

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

As a main limitation of this study, the lack of a placebo group must be mentioned, which was not included for ethical reasons because our patient population had already failed several treatment attempts.

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/34678497>