Clinical trial results:
Food Allergy Surpression Therapy during protection with Xolair

Summary

EudraCT number	2012-005625-78
Trial protocol	SE
Global end of trial date	31 October 2020

Results information

Result version number	v1 (current)
This version publication date	16 September 2022
First version publication date	16 September 2022

Trial information

Trial identification

Sponsor protocol code	FASTXP2013

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02402231
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Karolinska Institutet
Sponsor organisation address	Nobels väg 6, Stockholm, Sweden, 17177
Public contact	Caroline Nilsson, Karolinska Institutet, caroline.a.nilsson@regionstockholm.se
Scientific contact	Caroline Nilsson, Karolinska Institutet, caroline.a.nilsson@regionstockholm.se

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 October 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 October 2020
Global end of trial reached?	Yes
Global end of trial date	31 October 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective is to evaluate whether individualized omalizumab treatment in combination with oral immunotherapy monitored by CDsens could be an effective intervention for suppression of allergic reactions to peanut.

Protection of trial subjects:

The study was approved by the ethics committee in Stockholm; 2013/827-31/3, Swedish Drug Agency; 5.1-2013-46183. Patients and caregivers gave their written informed consent.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 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	Sweden: 23
Worldwide total number of subjects	23
EEA total number of subjects	23

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)	17
Adults (18-64 years)	6
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Severely peanut allergic adolescents, aged 12–19, were recruited in the Stockholm area, between Oct 2013 and October 2020.

Pre-assignment

Screening details:

Inclusion criteria were evident history of peanut-induced anaphylaxis within the last 5 years, anaphylaxis or symptoms of an impending anaphylaxis as defined by WAO at the open peanut challenge prior to inclusion. Exclusion criteria were severe non-atopic chronic disease, pregnancy or allergy/hypersensitivity to omalizumab.

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	Treatment group (one-armed study)

Arm description:

To evaluate whether individualized omalizumab treatment in combination with oral immunotherapy monitored by CDsens could be an effective intervention for suppression of allergic reactions to peanut.

Arm type	Experimental
Investigational medicinal product name	Xolair (omalizumab)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Phase 1: Severely peanut allergic adolescents (n = 23) were treated with omalizumab for 8 weeks, and CD-sens was analysed before and after. Based on whether CD-sens was suppressed after 8 weeks, the patients either were subject to a peanut challenge or received eight more weeks with increased dose of omalizumab, followed by peanut challenge or another 8-week cycle of omalizumab.
Phase 2: Started peanut oral immunotherapy (pOIT) after an individualized omalizumab treatment. The pOIT dose was increased from 280 to 2800 mg peanut protein in 8 weeks followed by an individualized stepwise withdrawal of omalizumab, based on clinical symptoms and CDsens levels. pOIT continued for 12 weeks followed by an open peanut challenge.7

Number of subjects in period 1	Treatment group (one-armed study)
Started	23
Completed	23

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	23	23	
Age categorical 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)	17	17	
Adults (18-64 years)	6	6	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
median	17		
full range (min-max)	12 to 19	-	
Gender categorical Units: Subjects			
Female	16	16	
Male	7	7	
IgE-ab Ara h 2 Units: kUA/L			
median	58		
full range (min-max)	16 to 220	-	

End points

End points reporting groups

Reporting group title	Treatment group (one-armed study)

Reporting group description:

To evaluate whether individualized omalizumab treatment in combination with oral immunotherapy monitored by CDsens could be an effective intervention for suppression of allergic reactions to peanut.

Primary: Tolerating peanuts 12 weeks after stopping omalizumab

End point title	Tolerating peanuts 12 weeks after stopping omalizumab[1]

End point description:

Primary endpoint: Number of patients who succeeded to eat 10 grams of peanuts 12 weeks after discontinuing pOIT (peanut oral immunotherapy) and omalizumab.
Treatment success: Patient succeeded to eat 10 grams of peanuts without an allercig reaction.
Treatment Failure: Patient did not suceed to eat 10 grams of peanuts without an allergic reaction.

End point type	Primary

End point timeframe:

12 weeks after discontinuing pOIT and omalizumab.

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 end point is reported in numbers (number of patients who succeded or failed the peanut challenge). Therefore, a statistical analysis cannot be performed.

End point values	Treatment group (one-armed study)			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: Number				
Treatment Success	11			
Treatment Failure	6			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

During the whole study period.

Adverse event reporting additional description:

Patients reported adverse events (AE) by phone and/or at visits. Frequencies of specific symptoms apart from mild selfresolving abdominal pain, mild emesis and oral pruritus were recorded. In case of emergency visits, medical records were independently reviewed by two physicians.

Assessment type	Systematic

Dictionary used

Dictionary name	Did not use any
Dictionary version	1

Reporting groups

Reporting group title	Treatment group (one-armed study)

Reporting group description:

To evaluate whether individualized omalizumab treatment in combination with oral immunotherapy monitored by CDsens could be an effective intervention for suppression of allergic reactions to peanut.

Serious adverse events	Treatment group (one-armed study)		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 17 (5.88%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Respiratory, thoracic and mediastinal disorders			
Allergic reactions	Additional description: Systemic allergic reactions Mild: ≥2 organ systems Moderate: ≥2 organ systems fulfilling the WAOcriteria for anaphylaxis and criteria for grade 12 anaphylaxis Severe: ≥2 organ systems fulfilling WAOcriteria for anaphylaxis and grade 3 anaphylaxis		
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Treatment group (one-armed study)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 17 (88.24%)		
Respiratory, thoracic and mediastinal disorders			

Allercig reactions	Additional description: Systemic allergic reactions Mild: ≥2 organ systems Moderate: ≥2 organ systems fulfilling the WAOcriteria for anaphylaxis and criteria for grade 12 anaphylaxis Severe: ≥2 organ systems fulfilling WAOcriteria for anaphylaxis and grade 3 anaphylaxis		
subjects affected / exposed	15 / 17 (88.24%)		
occurrences (all)	15		

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.

Weaknesses include the small study population and lack of placebo arm; all results should be considered as exploratory and need to be further studied. The main rationale for not having a placebo arm was patient safety.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/27883239

http://www.ncbi.nlm.nih.gov/pubmed/31329313