Clinical trial results:
Protection from food induced anaphylaxis by reducing serum level of specific IgE

Summary

EudraCT number	2017-003627-30
Trial protocol	DK
Global end of trial date	21 December 2020

Results information

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

Trial information

Trial identification

Sponsor protocol code	20170367744

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03964051
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Odense University Hospital
Sponsor organisation address	Kløvervænget 15, Odense, Denmark, 5000
Public contact	Carsten Bindslev-Jensen, Odense Research Center of Anaphylaxis (ORCA), 0045 65413624, carsten.bindslev-jensen@rsyd.dk
Scientific contact	Carsten Bindslev-Jensen, Odense Research Center of Anaphylaxis (ORCA), 0045 65413624, carsten.bindslev-jensen@rsyd.dk

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	19 May 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 December 2020
Global end of trial reached?	Yes
Global end of trial date	21 December 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim was to investigate if the combination of initial IgE-specific immunoadsorption and subsequent therapy with Omalizumab would increase the clinical threshold to the culprit food and thus prevent medical emergencies in patients with food anaphylaxis.

Protection of trial subjects:

All procedures performed in the study were standard procedures. No specific measures were needed to protect trial subjects.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2018
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	Denmark: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	10
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Trial subjects were recruited from patients followed in The Allergy Centre, Odense University Hospital, Odense, Denmark.
Recruitment period: 01-JUN-2018 - 22-FEB-2020.

Pre-assignment

Screening details:

Inclusion criteria were: 1) Age 18-70 years, 2) Verified food allergy with a specific IgE to the major allergen component of the culprit food of at least 10 kIU/l.
All patients screened (n=10) were eligible and participated in the study.

Pre-assignment period milestones

Number of subjects started	10
Number of subjects completed	10

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

Arm description:

Since the study was neither randomised nor controlled, there was just one study arm: All participants were planned to undergo the protocolled combined treatment of selective IgE apheresis followed by subsequent treatment with Omalizumab.

Arm type	Experimental
Investigational medicinal product name	OMALIZUMAB
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

All participants received a dosage of 300 mg Omalizumab a total of 7 times with 2 weeks interval between injections

Number of subjects in period 1	Treatment
Started	10
Food challenge Tr0	10
Food challenge TrP	8
Food challenge TrX	8
Food challenge TrW	7

Completed	7
Not completed	3
Consent withdrawn by subject	2
Adverse event, non-fatal	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	10	10	
Age categorical			
Age 18-64			
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)	0	0	
Adults (18-64 years)	10	10	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: years			
median	24		
inter-quartile range (Q1-Q3)	20 to 42	-	
Gender categorical			
Units: Subjects			
Female	6	6	
Male	4	4	

End points

End points reporting groups

Reporting group title	Treatment

Reporting group description:

Since the study was neither randomised nor controlled, there was just one study arm: All participants were planned to undergo the protocolled combined treatment of selective IgE apheresis followed by subsequent treatment with Omalizumab.

Primary: Fractional change in threshold (food challenge) between Tr0 and TrX (TrX/Tr0)

End point title	Fractional change in threshold (food challenge) between Tr0 and TrX (TrX/Tr0)[1]

End point description:

End point type	Primary

End point timeframe:

The threshold at food challenges (in milligrams) before any treatment (Tr0) was compared with threshold after the combined treatment with IgE apheresis and Omalizumab treatment (TrX). Change in threshold was expressed as a fraction/delta (TrX/Tr0)

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: This study was designed with no planned statistical analyses to be performed for any endpoints due to the simple design and small number of participants

End point values	Treatment			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Fractions				
median (inter-quartile range (Q1-Q3))	7.8 (3.2 to 22.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Fractional change in level of total IgE between Tr0 and TrX (TrX/Tr0)

End point title	Fractional change in level of total IgE between Tr0 and TrX (TrX/Tr0)[2]

End point description:

End point type	Primary

End point timeframe:

The level of total IgE before any treatment (Tr0) was compared with the level of total IgE after the combined treatment with IgE apheresis and Omalizumab treatment (TrX). Change in level of total IgE was expressed as a fraction/delta (TrX/Tr0)

Notes:

[2] - 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: This study was designed with no planned statistical analyses to be performed for any endpoints due to the simple design and small number of participants

End point values	Treatment			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Fractions				
median (inter-quartile range (Q1-Q3))	2.5 (1.2 to 2.7)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug to 28 days after last dose of study drug

Assessment type	Non-systematic

Dictionary used

Dictionary name	None
Dictionary version	0

Reporting groups

Reporting group title	Treatment

Reporting group description: -

Serious adverse events	Treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 8 (87.50%)		
Immune system disorders			
Rhinitis allergic	Additional description: Symptoms of well-known allergic rhinitis		
alternative assessment type: Systematic			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Eye disorders			
Conjunctivitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Gastrointestinal disorders			
Food allergy	Additional description: Allergic reaction due to accidental intake of a known food culprit (known food allergy)		
alternative assessment type: Systematic			

subjects affected / exposed	2 / 8 (25.00%)		
occurrences (all)	2		
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Asthma	Additional description: Mild exacerbation in prior diagnosed/well-known asthma		
alternative assessment type: Systematic			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Eczema	Additional description: Flair in prior diagnosed/well-known atopic dermatitis		
alternative assessment type: Systematic			
subjects affected / exposed	2 / 8 (25.00%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Infections and infestations			
Rhinitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Vaginitis viral			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Cystitis bacterial			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 8 (12.50%)		
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