Clinical trial results:
Anti-IL-17, a possible new treatment for contact dermatitis?

Summary

EudraCT number	2015-004494-33
Trial protocol	DK
Global end of trial date	13 June 2017

Results information

Result version number	v1 (current)
This version publication date	15 December 2022
First version publication date	15 December 2022
Summary attachment (see zip file)	manuscript II (Contact Dermatitis - 2018 - Todberg - The effect of treatment with antiinterleukin17 in patients with allergic contact.pdf) manuscript (Int J Dermatology - 2018 - Todberg - The effect of antiIL17 treatment on the reaction to a nickel patch test in patients.pdf)

Trial information

Trial identification

Sponsor protocol code	2015-004494-33

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Department of Dermatology and Allergy, Herlev and Gentofte Hospital, University of Copenhagen Denmark
Sponsor organisation address	Gentofte Hospitalsvej 15, 2900 Hellerup, Hellerup, Denmark, 2900
Public contact	Dept of dermato-allergology, Herlev and Gentofte Hospital, tanja.todberg@regionh.dk
Scientific contact	Dept of dermato-allergology, Herlev and Gentofte Hospital, +45 27366340, tanja.todberg@regionh.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	13 June 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 June 2017
Global end of trial reached?	Yes
Global end of trial date	13 June 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study will evaluate secukinumab treatment in patients with known allergic contact dermatitis. The study which is an interventional type will consist of two parts both performed at Department of Dermato-allergology, Herlev and Gentofte Hospital, University of Copenhagen, Hellerup, Denmark.

Study 1
Study 1 will include 10 patients with known allergy to nickel, but with no to low grade of eczema at inclusion.

1.Reduction in clinical patch test score for dermatitis after secukinumab treatment compared to patch test score before secukinumab treatment in patients challenged with nickel.

Protection of trial subjects:

GCP, Copenhagen

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 January 2016
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: 15
Worldwide total number of subjects	15
EEA total number of subjects	15

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)	15
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Herlev and Gentofte Hospital

Pre-assignment

Screening details:

- known contact allergy
-age + 18
-no other skin diseases

Period 1

Period 1 title	IL-17 ACD (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	IL-17
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	secukinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for cutaneous solution
Routes of administration	Subcutaneous use

Dosage and administration details:

secukimumab in approved dosis.

Number of subjects in period 1	IL-17
Started	15
Completed	15

Baseline characteristics

Reporting groups

Reporting group title	IL-17 ACD

Reporting group description: -

Reporting group values	IL-17 ACD	Total	
Number of subjects	15	15	
Age categorical			
Age 18-79			
Units: Subjects			
Adults (18-64 years)	14	14	
From 65-84 years	1	1	
Gender categorical Units: Subjects			
Female	7	7	
Male	8	8	

Subject analysis sets

Subject analysis set title	IL17
Subject analysis set type	Full analysis

Subject analysis set description:
to test effekt of il-17 on ACD

Reporting group values	IL17		
Number of subjects	15		
Age categorical			
Age 18-79			
Units: Subjects			
Adults (18-64 years)	14		
From 65-84 years	1		
Gender categorical Units: Subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	IL-17
Reporting group description: -	
Subject analysis set title	IL17
Subject analysis set type	Full analysis
Subject analysis set description: to test effekt of il-17 on ACD	

Primary: IL17

End point title	IL17[1]
End point description:	
End point type	Primary
End point timeframe: 1.Reduction in clinical patch test score for dermatitis after secukinumab treatment compared to patch test score before secukinumab treatment in patients challenged with nickel (21 days) 2. The effect of IL-17 in patients with severe ACD (16 weeks)	

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: Please not this is a single arm study, thus a statistical analysis is not mandatory

End point values	IL-17			
Subject group type	Reporting group			
Number of subjects analysed	15[2]			
Units: 1.1				
il-17	15			

Notes:

[2] - Subjects: 15

Attachments (see zip file)	article_1/Contact Dermatitis - 2018 - Todberg - The effect of article_2/Int J Dermatology - 2018 - Todberg - The effect of

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
+ 4 weeks after last dosis.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Reporting groups	
Reporting group title	IL-17

Reporting group description:

A flare-up of eczema was seen in one case, so prednisolone was administered to this patient in week 12. This patient and one other patient applied strong topical corticosteroid due to a lack of improvement in their eczema from week 2 in one case and from week 8 in the other. There were no severe adverse events. One patient experienced vertigo, and one patient had a debut of psoriasis during the trial.

Serious adverse events	IL-17		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0.5 %

Non-serious adverse events	IL-17		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 15 (13.33%)		
General disorders and administration site conditions			
Dermatitis			
subjects affected / exposed	2 / 15 (13.33%)		
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