



Clinical trial results:

The role of Interleukin-1B targeted therapy for patients suffering with allergic contact dermatitis: A randomized controlled trial with Anakinra vs. Placebo.

Summary

EudraCT number	2021-004750-39
Trial protocol	DK
Global end of trial date	27 October 2023

Results information

Result version number	v1 (current)
This version publication date	08 May 2025
First version publication date	08 May 2025

Trial information

Trial identification

Sponsor protocol code	LEOSIC
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Herlev Gentofte Hospital
Sponsor organisation address	Gentofte Hospitalsvej 15, Hellerup, Denmark,
Public contact	Kelvin Yeung, Herlev Gentofte Hospital. Department of Dermatology and Allergy, kelvin.yeung@sund.ku.dk
Scientific contact	Kelvin Yeung, Herlev Gentofte Hospital. Department of Dermatology and Allergy, kelvin.yeung@sund.ku.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 March 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 October 2023
Global end of trial reached?	Yes
Global end of trial date	27 October 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess if there is a clinical difference in severity of ACD in participants treated with anakinra compared to placebo measured by different scoring systems for ACD.

Protection of trial subjects:

Trial diary to register AE. Extra follow up visits. AE registration in the SOP for every visit.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2022
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	Denmark: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	20
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Potential participants were screened according to the trial protocol.

Pre-assignment period milestones

Number of subjects started	20
Number of subjects completed	20

Period 1

Period 1 title	First challenge
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Assessor

Arms

Are arms mutually exclusive? Yes

Arm title Placebo

Arm description:

NaCl solution 9 mg/ml

Arm type	Placebo
Investigational medicinal product name	Natriumklorid "Fresenius Kabi" 9 mg/ml
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

1 mL s.c. daily for 6 consecutive days

Arm title Kineret

Arm description:

Anakinra 100 mg/0,67 ml

Arm type	Experimental
Investigational medicinal product name	Kineret
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

100 mg daily s.c. for 6 consecutive days

Number of subjects in period 1	Placebo	Kineret
Started	8	12
Completed	8	12

Period 2

Period 2 title	Second challenge
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Natriumklorid "Fresenius Kabi" 9 mg/ml
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

1 mL s.c. daily for 6 consecutive days

Arm title	Kineret
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	Kineret
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

100 mg daily s.c. for 6 consecutive days

Number of subjects in period 2	placebo	Kineret
Started	8	12
Completed	8	12

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description: NaCl solution 9 mg/ml	
Reporting group title	Kineret
Reporting group description: Anakinra 100 mg/0,67 ml	

Reporting group values	Placebo	Kineret	Total
Number of subjects	8	12	20
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	8	12	20
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	36.6	39.8	
standard deviation	± 13.4	± 11.1	-
Gender categorical			
Units: Subjects			
Female	8	11	19
Male	0	1	1

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
NaCl solution 9 mg/ml	
Reporting group title	Kineret
Reporting group description:	
Anakinra 100 mg/0,67 ml	
Reporting group title	placebo
Reporting group description: -	
Reporting group title	Kineret
Reporting group description: -	

Primary: Participants achieving reduction in International Contact Dermatitis Research Group score

End point title	Participants achieving reduction in International Contact Dermatitis Research Group score
End point description:	Number of participants achieving a reduction in International Contact Dermatitis Research Group score during second challenge. Reactions can be scored as negative reaction (-), doubtful reaction (?+), weak positive reaction (+), strong positive reaction (++) , extreme positive reaction (+++).
End point type	Primary
End point timeframe:	International Contact Dermatitis Research Group scores during first challenge

End point values	Placebo	Kineret		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	12		
Units: Subjects				
Baseline: Doubtful reaction	1	1		
Baseline: Weak positive reaction	4	8		
Baseline: Strong positive reaction	2	3		
Baseline: Extreme positive reaction	1	0		

Statistical analyses

Statistical analysis title	Fischer exact test with dunn bonferroni correction
Statistical analysis description:	Since neither group had any participants with a reduction in ICDRG score, there is no evidence of a difference between the treatment and placebo groups. The p-value greater than 0.05 confirms that the two groups are statistically identical in this outcome. However, this result is also limited by the small sample size and the absence of any events, meaning no meaningful conclusion about treatment efficacy can be drawn from this test alone.
Comparison groups	Placebo v Kineret

Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Fisher exact

Primary: Participants achieving reduction in International Contact Dermatitis Research Group score

End point title	Participants achieving reduction in International Contact Dermatitis Research Group score
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End point description:

Number of participants achieving a reduction in International Contact Dermatitis Research Group score during second challenge. Reactions can be scored as negative reaction (-), doubtful reaction (?+), weak positive reaction (+), strong positive reaction (++), extreme positive reaction (+++).

End point type	Primary
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End point timeframe:

International Contact Dermatitis Research Group score during second challenge

End point values	placebo	Kineret		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	12		
Units: Subjects				
Second challenge: Doubtful reaction	0	0		
Second challenge: Weak positive reaction	0	0		
Second challenge: Strong positive reaction	4	5		
Second challenge: Extreme positive reaction	4	7		

Statistical analyses

Statistical analysis title	Fischer exact test with dunn bonferroni correction
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Statistical analysis description:

Since neither group had any participants with a reduction in ICDRG score, there is no evidence of a difference between the treatment and placebo groups. The p-value greater than 0.05 confirms that the two groups are statistically identical in this outcome. However, this result is also limited by the small sample size and the absence of any events, meaning no meaningful conclusion about treatment efficacy can be drawn from this test alone.

Comparison groups	placebo v Kineret
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Fisher exact

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Day 20 and until end of trial period

Assessment type	Systematic
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Dictionary used

Dictionary name	SNOMED CT
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Dictionary version	2022
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

NaCl solution 9 mg/ml

Reporting group title	Kineret
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Reporting group description:

Anakinra 100 mg/0,67 ml

Serious adverse events	Placebo	Kineret	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Placebo	Kineret	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: None of the 20 participants experienced any AE to treatment or placebo. None was reported during the study period.

This was expected since the study drug is well-known and well-tolerated and are used daily in the clinic for long periods of time to treat certain dermatological diseases. The most well-known AE are infections during long-term treatment. In our study the participants only received treatment for 6 consecutive days and none developed AE in this short study period.

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