



Clinical trial results: Ilaris (Canakinumab) in the Schnitzler syndrome : A Case series Summary

EudraCT number	2010-023603-10
Trial protocol	BE
Global end of trial date	30 June 2019

Results information

Result version number	v1 (current)
This version publication date	12 March 2023
First version publication date	12 March 2023

Trial information

Trial identification

Sponsor protocol code	S52762
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	UZ Leuven
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	Prof Steven Vanderschueren, UZ Leuven,, steven.vanderschueren@uzleuven.be
Scientific contact	Prof Steven Vanderschueren, UZ Leuven,, steven.vanderschueren@uzleuven.be

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	30 June 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 June 2019
Global end of trial reached?	Yes
Global end of trial date	30 June 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate if canakinumab 150mg every 8 weeks can induce and maintain clinical remission in patients with the Schnitzler syndrome.

Protection of trial subjects:

subcutaneous injections and peripheral blood sampling are done by trained study nurses to minimise pain and distress

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 May 2011
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	8 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 1
Worldwide total number of subjects	1
EEA total number of subjects	1

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)	1
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

One patient was recruited on 5 May 2011.

Pat was followed up in the trial until 30 June 2019 , when the trial ended.

Pre-assignment

Screening details:

only one patient fulfilled all inclusion criteria: diagnosed with Schnitzler syndrome

Period 1

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

Arms

Arm title	canakinumab arm
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Arm description:

treatment with canakinumab ,open label

Arm type	Experimental
Investigational medicinal product name	canakinumab
Investigational medicinal product code	ATC L04AC08
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

150 -300 mg every 4 to 8 weeks, subcutaneous injections

Number of subjects in period 1	canakinumab arm
Started	1
Completed	1

Baseline characteristics

Reporting groups

Reporting group title	one patient trial
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Reporting group description:

patient diagnosed with Schnitzler Syndrome

Reporting group values	one patient trial	Total	
Number of subjects	1	1	
Age categorical			
one adult patient			
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)	1	1	
From 65-84 years	0	0	
85 years and over	0	0	
adult	0	0	
Gender categorical			
male patient, adult			
Units: Subjects			
Female	0	0	
Male	1	1	

End points

End points reporting groups

Reporting group title	canakinumab arm
Reporting group description: treatment with canakinumab ,open label	

Primary: clinical remission

End point title	clinical remission ^[1]
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End point description:

This therapy is expected to induce a response as long as administration continues. Symptoms (including high-grade relapsing fevers, chronic urticaria, bone and joint pains) and signs (chronic lab inflammatory syndrome) are likely to recur after the cessation of therapy has ended.

End point type	Primary
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End point timeframe:

28 weeks,(prolongation of therapy 18 months)

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: no statistical analyses as only 1 patient is included in the trial

End point values	canakinumab arm			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: clinical evaluation				
number (not applicable)				
resolution of signs and symptoms	1			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:
during the entire trial

Assessment type	Non-systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	1
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Reporting groups

Reporting group title	canakinumab arm
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Reporting group description:

treatment with canakinumab ,open label

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: Indeed, No non serious adverse events were recorded,

Serious adverse events	canakinumab arm		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Infections and infestations			
epididymitis			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	canakinumab arm		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		

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

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/22901459>