Clinical trial results:
STRAUSS: responSe To ustekinumab foR Anti-tnf IndUced pSoriasiform Skin lesions

Summary

EudraCT number	2018-003189-15
Trial protocol	BE
Global end of trial date	10 October 2024

Results information

Result version number	v1 (current)
This version publication date	26 October 2024
First version publication date	26 October 2024

Trial information

Trial identification

Sponsor protocol code	S61472

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03629379
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University Hospitals Leuven
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	Clinical Trial Center UZ Leuven, University Hospitals Leuven, +32 1634 19 98, ctc@uzleuven.be
Scientific contact	Clinical Trial Center UZ Leuven, University Hospitals Leuven, +32 1634 19 98, ctc@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	Interim
Date of interim/final analysis	10 October 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 October 2024
Global end of trial reached?	Yes
Global end of trial date	10 October 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this prospective, observational study is to indentify transcriptomic and proteomic signatures, which can predict good response to ustekinumab in anti-TNF treated patients with psoriasiform skin lesions

Protection of trial subjects:

No specific requirements are necesarry

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2018
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	Belgium: 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)	8
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

We will prospectively include patients with crohn's disease or ulcerative colitis, who develop psoriasiform skin lesions (including psoriasiform eczema, psoriasis guttata, psoriasis inversa and pustulosis) under therapy with anti-TNF and refractory to at least 12 weeks of topical therapy.

Pre-assignment

Screening details:

IBD patients not treated with anti-TNF therapy or IBD patients with paradoxical skin lesions due to anti-TNF who are not refractory to topical therapy were excluded.
Patients who previously received anti-IL12/23 or anti-IL23 therapy or vedolizumab were excluded.
Pregnant IBD patients were excluded.

Period 1

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

Blinding implementation details:

Study was not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	vedolizumab therapy

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	vedolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for concentrate for solution for infusion
Routes of administration	Infusion

Dosage and administration details:

intravenous vedolizumab 300mg at weeks 0, 2, 6, 14

Arm title	ustekinumab therapy

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	ustekinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion, Suspension for injection in pre-filled syringe
Routes of administration	Infusion , Injection

Dosage and administration details:

standard induction with intravenous ustekinumab of 6mg/kg, followed by subcutaneous injection of 90mg every 8 weeks

Number of subjects in period 1	vedolizumab therapy	ustekinumab therapy
Started	5	5
Completed	5	5

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 Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
All patients patients with inflammatory bowel disease aged 18 to 80-years-old			
Units: years			
median	49.5		
inter-quartile range (Q1-Q3)	36.0 to 64.3	-	
Gender categorical			
Both female and male patients were included			
Units: Subjects			
Female	5	5	
Male	5	5	

End points

End points reporting groups

Reporting group title	vedolizumab therapy
Reporting group description: -	
Reporting group title	ustekinumab therapy
Reporting group description: -	

Primary: chnages in transcriptomic and proteomic signatures

End point title	chnages in transcriptomic and proteomic signatures[1]

End point description:

The primary objective of this prospective, interventional study is to identify transcriptomic and proteomic signatures, which can predict good response to UST in anti-TNF treated patients with inflammatory skin lesions.

End point type	Primary

End point timeframe:

14 weeks if patients receive vedolizumab or 16 weeks if patients receive ustekinumab

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: Proof of concept trial. No statistical analyses was feasible due to limited patient recruitment.

End point values	vedolizumab therapy	ustekinumab therapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	5		
Units: whole				
reduction lesion	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

16 weeks

Assessment type	Systematic

Dictionary used

Dictionary name	SNOMED CT
Dictionary version	20240901

Reporting groups

Reporting group title	Ustekinumab
Reporting group description: -	
Reporting group title	vedolizumab
Reporting group description: -	

Serious adverse events	Ustekinumab	vedolizumab	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (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: 1 %

Non-serious adverse events	Ustekinumab	vedolizumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (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: No adverse events

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.

Power of study limted due to difficulty in patient recruitment

Notes: