



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: changes in transcriptomic and proteomic signatures

| | |
|---|---|
| End point title | changes 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.

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|---|
| Power of study limited due to difficulty in patient recruitment |
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Notes: