A Phase 1, Open-label, Single-dose, Randomized, Crossover Study to Assess the Local Tolerability of the Tildrakizumab 200 mg Dose when Delivered as Single Subcutaneous Injection via the 200 mg/2 mL Pre-filled Syringe

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Ethical review	Approved WMO
Status	Completed
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON49835

Source
ToetsingOnline

Brief title
Tolerability Study with Tildrakizumab 200 mg Dose

Condition

- Epidermal and dermal conditions

Synonym
Psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Almirall
Source(s) of monetary or material Support: Pharmaceutical Industry

Intervention

Keyword: psoriasis, tildrakizumab, tolerability

Outcome measures

Primary outcome

To assess the local tolerability of the tildrakizumab 200-mg dose when

administered as a single 200 mg/2 mL SC injection or as two 100 mg/1 mL SC

injections in healthy subjects.

Secondary outcome

To assess the safety of the tildrakizumab 200-mg dose when administered as a

single 200 mg/2 mL SC injection or as two 100 mg/1 mL SC injections in healthy

subjects.

To assess the subjects* preferred method of administration of the tildrakizumab

200-mg treatments (single 2 mL or two 1 mL injections).

Study description

Background summary

Tildrakizumab is a compound that is being used for the treatment of psoriasis. Psoriasis is a chronic skin disease where red, dry, and scaly patches are present on the skin. These patches are most often found on the elbows, knees, and head, and can cause severe itching and pain. Tildrakizumab belongs to a

group of medicines called interleukin (IL) inhibitors. These medicines work by blocking the activity of a protein called IL-23, a substance in the body which is involved in normal inflammatory and immune responses. In psoriasis, IL-23 is present at increased levels. By reducing the activity of IL-23, tildrakizumab reduces the inflammatory processes and thereby the signs and symptoms of psoriasis.

Study objective

The purpose of this study is to investigate how well a new dosage form of tildrakizumab is tolerated when it is administered to healthy volunteers. Tildrakizumab (also known as Ilumetri) is no new compound; it is already available on the market as a 1 milliliter injection with a fixed dose of 100 mg tildrakizumab per syringe. Tildrakizumab therefore has been administered to humans before. It has previously also been extensively tested in the laboratory and on animals. Patients with more severe psoriasis or patients with higher body weights may benefit from a higher dose. Therefore, the purpose of this study is to investigate the tolerability of 200 mg tildrakizumab when it is given as a 2 milliliter injection.

Study design

The volunteer receives 200 mg of tildrakizumab twice. Tildrakizumab is given once as 1 injection and once as 2 injections. The test substance will be administered under the skin (subcutaneously) in the volunteer's arm, thigh, or abdomen. The treatment will be administered in the morning after eating a standard breakfast. If the volunteer receives 2 injections, the second injection will be given immediately after the first.

The order in which the volunteer receives the treatment will be random (will be determined by drawing lots). Whether the volunteer gets the injection into your arm, thigh, or abdomen will also be randomly assigned.
• Treatment A: 1 injection of 2 mL, administered in the left or right arm or thigh, or in the left or right side of the abdomen.
• Treatment B: 2 injections of 1 mL, both administered in different arms or thighs, or in different sides of the abdomen

Intervention

The volunteer receives 200 mg of tildrakizumab twice. Tildrakizumab is given once as 1 injection and once as 2 injections. The test substance will be administered under the skin (subcutaneously) in the volunteer's arm, thigh, or abdomen. The treatment will be administered in the morning after eating a standard breakfast. If the volunteer receives 2 injections, the second injection will be given immediately after the first

Study burden and risks

Tildrakizumab is no new compound and has been administered to humans before. It has been given to 2190 subjects in previous clinical trials and was found to effectively improve the signs and symptoms of psoriasis in patients. Furthermore it was found that tildrakizumab was generally safe and well tolerated.

The following side effect was most frequently observed (in more than 1 in 10 people):
• Infection of the upper respiratory tract (including nose cold [nasopharyngitis])

The following side effects were also observed (in less than 1 in 10 people):
• Pain at the injection site
• Headache
• Stomach flu (gastroenteritis), nausea or diarrhea
• Back pain

There is a chance that the body may develop antibodies against tildrakizumab. This means that, if the volunteer need to be treated with tildrakizumab in the future, the drug does not work or works less well. However, the chance that this will happen is very small and there are plenty of alternative drugs available that are still effective. Moreover, no relationship between the development of antibodies against Ilumetri and the way the drug works or its side effects was observed in studies with patients.

The study compound may also have side effects that are still unknown. In addition to unknown side effect, there is a (small) chance that an allergic reaction will occur. This can be caused by the study compound or the excipients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Men or women must be between 18 and 60 years, inclusive, at screening.
2. Body mass index (BMI) must be between 18.0 and 30.0 kg/m2, inclusive, at screening.
3. Subjects must be able to understand and comply with the requirements of the study and communicate with the Investigator.
4. Subjects must give a written, signed, and dated informed consent including authorization for Use and Release of Health and Research Information in accordance with institutional and regulatory guidelines before any study-related activity is performed.
5. Subjects are in good general health on the basis of medical history, physical examination, clinical laboratory, ECG, and vital signs, as judged by the Investigator.

For the complete overview see the protocol

Exclusion criteria

1. Any condition that could interfere with delivery of medication or interpretation of assessments or significantly impair pain perception at any of the anatomical sites for injection (upper arms, thighs, abdomen).
2. History of or current malignancy (excluding successfully treated basal cell carcinoma, squamous cell carcinoma of the skin in situ, squamous cell carcinoma with no evidence of recurrence within 5 years or carcinoma in situ of the cervix that has been adequately treated).

3. History of or current relevant autoimmune diseases (e.g., lupus-like syndromes).
4. Clinically significant skin allergies or active dermatologic disorders.
5. Hypersensitivity to the active substance or to any of the excipients of the investigational medicinal product (IMP).

For the complete overview see the protocol

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-09-2020
Enrollment:	42
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ilumetri
Generic name:	Tildrakizumab
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	18-03-2020
Application type:	First submission

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-04-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-08-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2020-000183-37-NL
CCMO	NL73105.056.20

Study results

Date completed:	19-03-2021
Results posted:	02-07-2021

First publication
04-06-2021