A randomized, open-label, two-period, crossover study to determine the pharmacokinetics of reconstituted lyophilized Erelzi and Enbrel® (US-licensed) following a single subcutaneous injection in healthy male subjects.

Published: 20-06-2018
Last updated: 11-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON45782

Source
ToetsingOnline

Brief title
Erelzi/Enbrel bioequivalence study.

Condition

- Joint disorders

Synonym
rheumatoid arthritis

Research involving

Human

Sponsors and support

Primary sponsor: Hexal AG
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: ankylosing spondylitis, Erelzi and Enbrel®, juvenile idiopathic arthritis, rheumatoid arthritis

Outcome measures

Primary outcome

To demonstrate PK similarity between Erelzi LYVI/US and Enbrel LYVI/US

following a single s.c. injection of 18 mg.

Secondary outcome

- To compare additional PK parameters between Erelzi LYVI/US and Enbrel LYVI/US

following a single s.c. injection

- To evaluate and compare the immunogenicity of both products

- To evaluate and compare the safety, tolerability and injection site reactions

(ISR) of both products

Study description

Background summary

This study will compare the study drug Erelzi powder to a similar product which is already on the market in US, namely Enbrel® powder referred to as comparator drug.

The study drug and the comparator drug contain the same active ingredient called etanercept. Etanercept inhibits inflammatory reactions by binding to a cytokine involved in inflammation, called TNF- (a cytokine is a small protein involved in the communication between many different kinds of cells in the

human body).

Study objective

The purpose of the study is to compare these two drugs in view of how quickly and to what extent the drugs are absorbed and eliminated from the body (this is called pharmacokinetics) after injection under the skin of the abdomen.
In addition, it will be analysed to which degree the study drug is provoking an immune response.
It will also be investigated how safe the study drug is and how well it is tolerated after dosing.

This study is the first time that this new form of the study drug is being given to humans.

Study design

The volunteers will arrive at the research center at 2 pm in the afternoon prior to the administration of the research instrument (Day 1). The day that the research drug is administered is called Day 1.

If the research physician has established that the volunteer is in good health and there are no doubts about safety, then leave the research center after all measurements on Day 6 have been completed. In both treatment periods one must return five times for measurements in the research center on Days 8, 10, 12, 15 and 19.

During the study, one subcutaneous (under the skin) injection of 0.8 milliliter (ml) (consisting of 18 milligrams [mg]) solution of the test or comparison product into the abdomen is administered in each treatment period. This is a so-called crossed study, which means that if one gets the research tool (Erelzi solution) in Treatment Period 1, one gets the comparison product (Enbrel solution) in Treatment Period 2, or vice versa. The order in which Erelzi and Enbrel are awarded is determined by drawing lots, such as throwing a cup or coin.

Intervention

Not applicable.

Study burden and risks

Pain, minor bleedings, bruises, possibly an infection.

Contacts

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Scientific
Hexal AG

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Male subjects
18 to 55 years, inclusive
Weight 50 - 99.9 kg
BMI 19.0 - 29.9 kg/m2 inclusive ;5. Subject is affiliated with social security or equivalent system

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months

prior the start of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-06-2019
Enrollment:	56
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Etanercept
Generic name:	Enbrel®
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Etanercept
Generic name:	Erelzi®
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	20-06-2018

Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-08-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-10-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-05-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-05-2020
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	EUCTR2017-003828-76-NL
CCMO	NL66314.056.18