A randomized, open label, two-way cross-over study to determine the pharmacokinetics and safety of GP2015 following a single subcutaneous injection by an autoinjector and by a pre-filled syringe in healthy male subjects

Published: 04-03-2014
Last updated: 20-04-2024

Primary objective:To demonstrate bioequivalence of GP2015 applied by an autoinjector (delta-GP2015_50) and a pre-filled syringe (PFS) as single subcutaneous injection of 50 mg to healthy adult male subjectsSecondary objectives- To study and compare...

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

Summary

ID

NL-OMON40923

Source
ToetsingOnline

Brief title
GP2015 bioequivalence study

Condition

- Autoimmune disorders

Synonym
autoimmune diseases, rheumatoid arthritis

Research involving

Human

Sponsors and support

Primary sponsor: Hexal AG
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: Bioequivalence

Outcome measures

Primary outcome

Bioequivalence

Secondary outcome

Pharmacokinetics and safety and tolerability.

Study description

Background summary

GP2015 is a new investigational compound that is being developed as a copy of Enbrel®, a drug already approved for the treatment of certain autoimmune diseases, including Rheumatoid Arthritis and Psoriasis. The aim for GP2015 is to be approved for the treatment of the same autoimmune diseases as Enbrel®. Autoimmune diseases arise from an abnormal immune response of the body against substances and tissues normally present in the body. GP2015 inhibits inflammatory reactions by binding to certain proteins in the body, which decreases the immune response. Specifically, it interferes with the working of a cytokine involved in inflammation, called TNF-alpha (a cytokine is a small protein involved in the communication between many different kinds of cells in the human body).The active substance of GP2015 (and Enbrel®) is called etanercept, and consists of several parts (building blocks) that are naturally present in the human body. Therefore, the drug is called *a biological*. GP2015 is not registered as a drug, but has been given to humans before in other clinical studies.

Study objective

Primary objective:

To demonstrate bioequivalence of GP2015 applied by an autoinjector (delta-GP2015_50) and a pre-filled syringe (PFS) as single subcutaneous injection of 50 mg to healthy adult male subjects

Secondary objectives
- To study and compare delta-GP2015_50 and pre-filled syringe (PFS) for the PK parameters by weight catagory
- To evaluate the overall safety, tolerability and local tolerance

Study design

The study will be conducted in maximally 51 healthy male volunteers, divided into two periods. After each period, the volunteers will come back for five ambulant visits.

During the study, blood samples are regularly taken for PK and ADA (please refer to the protocol). Also physical examinations, ECGs and clinical chemical laboratory will be performed on several pre-defined timepoints..

Intervention

On day 1 of each period, a single dose of 50mg GP2015 subcutaneous injection via an auto-injector or an syringe is administered.

Study burden and risks

All potential drugs cause adverse events; the extent to which this occurs differs. GP2015 is a drug that affects the immune system, and may lower the ability of the immune system to fight infections or make any infection that a person may have worse (including serious infections). Allergic reactions may happen, with symptoms like hives, swelling of the face, eyes, lips or mouth, or trouble with breathing.

GP2015 has been given to healthy volunteers before, in clinical studies that compared it to Enbrel®. In those studies, the most frequent adverse events were infections of the nose and throat, headache, injection site reaction, and throat pain. There were also cases of reduction of the number of neutrophils (a kind of white blood cell involved in fighting infections). All these adverse events occurred with similar frequency after administration of GP2015 or Enbrel®.

Enbrel® is approved in many countries for the treatment of several autoimmune diseases, and therefore a significant amount of safety information has been collected about its use with patients. The most frequently reported adverse reactions with Enbrel® are: injection site reactions (such as pain, swelling, itching, reddening and bleeding at the puncture site), infections (such as ear

nose and throat infections, bronchitis, bladder infections and skin infections), allergic reactions, development of auto antibodies (antibodies against substances and tissues of the body), rash with or without itching, and/or fever.

More serious adverse reactions have been reported with Enbrel®. These include the occurrence of cancer (skin cancer, blood cancer and solid tumors), serious infections including tuberculosis and reactivation of viral hepatitis, and serious allergic reactions. Nervous system problems have been reported leading to symptoms including numbness and weakness of the body, vision problems and dizziness. Blood problems may occur and your body may not make enough of the blood cells that help fight infections or help to stop bleeding. Symptoms may include persistent fever, bruising or bleeding very easily, or looking very pale. New heart failure or worsening of a pre-existing heart failure may occur with symptoms like shortness of breath, swelling of the ankles or feet, or sudden weight gain.

Most of the adverse events reported for Enbrel® occurred in patients being treated for pre-existing inflammatory diseases like arthritis and psoriasis. In this study with healthy volunteers, only two doses of GP2015 will be administered. Therefore, it is thought that the probability of these events to happen is lower, and no serious adverse effects are expected.

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

- Subjects must give written informed consent before any assessment is performed;- Male subjects, aged 18 to 55 years inclusive ;- Physically and mentally healthy, as determined by physical examination and safety laboratory;- Body weight between 50 to 140 kg and body mass index (BMI) between 18.5 to 49.9 kg/m2 inclusively;- Non-smoker or ex-smoker, defined as not having smoked for at least 6 months before IMP administration

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):	12-03-2014
Enrollment:	51
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	GP2015
Generic name:	GP2015

Ethics review

Approved WMO Date:	04-03-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-03-2014
Application type:	First submission
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	EUCTR2013-004901-24-NL
CCMO	NL48169.056.14