A randomized, open-label, single-dose parallel-group trial to determine the pharmacokinetics and safety of GP2017 following a single subcutaneous injection by an autoinjector or by a pre-filled syringe in healthy male subjects

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

Summary

ID

NL-OMON42002

Source
ToetsingOnline

Brief title
GP2017 biosimilar study

Condition

- Autoimmune disorders

Synonym
autoimmune diseases, including rheumatoid arthritis and psoriasis

Research involving

Human

Sponsors and support

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

Intervention

Keyword: GP2017, Humira biosimilar, PK, Safety

Outcome measures

Primary outcome

To describe pharmacokinetics of GP2017 administered by an autoinjector

(delta-GP2017_40) or a PFS as a single subcutaneous

injection of 40 mg to healthy adult male subjects with body weights between

50.0 * 94.9 kg in terms of the pharmacokinetic parameters

AUC0*360h and Cmax.

Secondary outcome

* Pharmacokinetic parameters in subjects with body weights

between 50.0 * 94.9kg in terms of AUC0*last, AUC0**

* Pharmacokinetic parameters in subjects with body weights

between 50.0 * 94.9kg in terms of %AUCextrap, tmax, CL0*last, kel

and t1/2.

* All pharmacokinetic parameters within following weight

categories (50.0-64.9 kg, 65.0-79.9 kg, 80.0-94.9 kg, 95.0-

140.0 kg)

* Overall safety, immunogenicity, tolerability and local tolerance

Study description

Background summary

GP2017 is a new investigational compound that is being developed as a copy of Humira®, a drug already approved for the treatment of certain autoimmune diseases, including rheumatoid arthritis and psoriasis. The aim for GP2017 is to be approved for the treatment of the same autoimmune diseases as Humira®. Autoimmune diseases arise from an abnormal immune response of the body against substances and tissues normally present in the body. GP2017 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-* (a cytokine is a small protein involved in the communication between many different kinds of cells in the human body).The active substance of GP2017 (and Humira®) is called *adalimumab*, and consists of several parts (building blocks) that are naturally present in the human body. Therefore, the drug is called *a biological*. Since the active substance of both GP2017 and Humira® is adalimumab, it is expected that the treatment effect of GP2017 will be similar in comparison to Humira®. GP2017 is not registered as a drug, but has been given to humans before in other clinical studies.

Study objective

The purpose of the study is to investigate how quickly and to what extent GP2017 is absorbed and eliminated from the body (this is called pharmacokinetics) after a single injection under the skin of the abdomen. This injection is administered by either an autoinjector (a medical device for injecting a drug) or a pre-filled syringe, to see whether the pharmacokinetics is comparable for both administration methods. It will also be investigated to what extent GP2017 is safe and tolerated. Finally, the formation of antibodies against adalimumab will be investigated.

Study design

The study will consist of 1 period during which you will receive one single subcutaneous injection of 40 mg GP2017 diluted in 0.8 ml solution. GP2017 will be given either by an autoinjector or by a pre-filled syringe. The administration method by which you will receive GP2017 is chosen by chance. At Day 1 the volunteer will receive GP2017 within 1-2 hours after breakfast. The volunteer will stay in the clinical research center in Zuidlaren for 11 days (10 nights; from Day -1 to Day 10), followed by a period of 62 days during which he will visit the clinical research center in Zuidlaren for 6 short visits on Days 16, 23, 30, 44, 58 and 72 (the post-study screening will be on Day 72).

During the first 4 hours after administration of study medication he will be required to lie down in bed, because another position may influence the uptake of the drug.

Intervention

The study will consist of 1 period during which the volunteer will receive one single subcutaneous injection of 40 mg GP2017 diluted in 0.8 ml solution on Day 1.

Study burden and risks

The overall risks of GP2017 administration are considered to be minimal, although some are unforeseeable as this is still an early stage in the testing of this drug in man.
The first trial with GP2017 in healthy volunteers was conducted recently. In total, 73 volunteers received GP2017 injections. The study revealed that the adverse effects of 40 mg of GP2017 did not differ from Humira®. Adverse effects of GP2017 were similar to the adverse effects of volunteers who received marketed product Humira®. Adverse effects which were observed in this study in more than 10% of volunteers were headache, common cold, muscle ache, and abdominal pain. The majority of adverse effects were mild. With the dose used in this study no serious adverse effects are expected, but as all drugs may potentially cause adverse events to some extent the occurrence of known or other effects cannot be excluded.

Humira® is now marketed in the European Union and in USA for at least 10 years. The following list represents most of the side effects known for adalimumab, reported by patients with pre-existing inflammatory diseases like rheumatoid arthritis and psoriasis who were treated with multiple doses of Humira® and over longer time periods. Because this study includes only healthy volunteers who will receive a single dose, the probability of any of the following events to happen is considered low in this study.
- Adalimumab is a medicine that affects the immune system and can lower the ability of the immune system to fight infections or make any infection worse (including serious infections).
- Allergic reactions can happen with symptoms like hives, swelling of your face, eyes, lips or mouth, trouble with breathing.
- Nervous system problems with signs and symptoms that include: numbness or tingling of legs, arms and/or fingers, problems with your vision, weakness in your arms or legs, and dizziness, can occur.
- Blood dyscrasias (an imbalance of components of the blood) may occur in case the body does not make enough of the blood cells that help fight infections or help to stop bleeding. Symptoms can include fever that does not go away, 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 ankles or feet, sudden weight gain.
- Immune reactions have been reported and symptoms may include chest discomfort or pain that does not go away, shortness of breath, joint pain, or a rash on the cheeks or arms that gets worse in the sun.
- Liver problems can happen in people who use adalimumab. Possible symptoms are: feel very tired, skin or eyes look yellow, poor appetite or vomiting, pain on the right side of the stomach (abdomen).
- Some people using adalimumab had new onset of psoriasis. Tell the principal investigator if you develop red scaly patches or raised bumps that are filled with pus.
- In patients taking adalimumab on a long term basis, occurrence of cancer has been reported, e.g. skin cancer (generally not life-threatening if treated) or blood cancer and solid tumors (with a frequency of less than 1% of all patients).
However, the most common side effects for adalimumab are:
- Injection site reactions (redness, rash, swelling, itching, or bruising; these symptoms usually will go away within a few days), infections (such as upper respiratory tract infections and sinus infections), headaches, nausea (feeling unwell) and vomiting, rash and musculoskeletal pain (pain in the muscles and bones).

GP2017 is a so-called *biological*; with respect to the properties of these drugs there is a chance that the volunteers body will develop antibodies against adalimumab or that a hypersensitivity reaction will be induced. Based on experience with Humira® and an earlier study with GP2017, the chance that he will develop antibodies against adalimumab is likely. Should he develop antibodies, this is not expected to have consequences for his health. However, in case he would develop a condition that could be treated with adalimumab in the future, it cannot be predicted whether and how these antibodies may influence the effect of treatment. Currently, the following conditions could be treated with adalimumab: rheumatoid arthritis, ankylosing spondylitis, axial spondyloarthritis, psoriatic arthritis, psoriasis, Crohn*s disease, and ulcerative colitis. In that case, his doctor will suggest the best possible treatment. As of today several medications are available for the treatment of the conditions mentioned above with a mode of action, efficacy and safety profile which is similar to adalimumab.

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

- healthy male volunteers
- age 18 - 55 inclusive
- BMI between 18.0 and 49.9 kilograms/meter2
- weight between 50.0 and 140.0 kg

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 60 days before the start of this study or being a blood donor within 12 weeks from the start of the study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-01-2015
Enrollment:	108
Type:	Actual

Ethics review

Approved WMO Date:	01-12-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-01-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-02-2015
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	EUCTR2014-002879-29-NL
CCMO	NL51630.056.14