A randomized, 2 part, 4-treatment, 2-way cross-over study in healthy volunteers to compare the pharmacokinetic and pharmacodynamics profiles of 1 *g/kg of DA-3880 and EU sourced AND EU Aranesp® (AMGEN) after single intravenous or subcutaneous administration

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Red blood cell disorders
Study type	Interventional

Summary

ID

NL-OMON41044

Source
ToetsingOnline

Brief title
DA-3880 bio-similarity study

Condition

- Red blood cell disorders

Synonym
anemia

Research involving
Human

Sponsors and support

Primary sponsor: Dong-A ST Co., Ltd.
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: biological, DA-3880

Outcome measures

Primary outcome

To demonstrate bioequivalence of DA-3880, and EU sourced Aranesp® (Amgen) after administration of 1 µg/kg as a single iv dose in terms of PK parameters

To demonstrate bioequivalence of DA-3880, and EU sourced Aranesp® (Amgen) after administration of 1 µg/kg as a single sc dose in terms of PK parameters

Secondary outcome

To compare the PD of DA-3880 and EU sourced Aranesp® after administration of 1 µg/kg as a single iv dose and as a single sc dose

To compare the safety, tolerability and immunogenicity of DA-3880 and EU sourced Aranesp® after administration of 1 µg/kg as a single iv dose and as a single sc dose

To compare the PK and PD of DA-3880 (1 µg/kg) and EU sourced Aranesp® (1 µg/kg) after iv administration with those after sc administration

To compare the safety, tolerability and immunogenicity of DA-3880 (1 µg/kg) and EU sourced Aranesp® (1 µg/kg) after iv administration with those after sc

administration

Study description

Background summary

Aranesp® is a drug registered for the treatment of symptomatic anemia in patients with chronic renal failure, and patients receiving chemotherapy for the treatment of cancer. Aranesp® is the brand name, the active ingredient is called darbepoetin-*, which is a modified human erythropoietin (EPO). EPOs regulate the growth and maturation of red blood cells.

DA-3880 is developed to be a copy of Aranesp®. DA-3880 consists of several parts (building blocks) that are present in the human body by nature (like the building blocks of Aranesp®). Therefore, the drug is called *a biological*.
This is the first time that the DA-3880 compound is being given to humans.

Study objective

The purpose of the study is to investigate to what extent DA-3880 is absorbed and eliminated from the body (this is called pharmacokinetics) as compared to the above mentioned Aranesp® formulation. In addition, the effect DA-3880 on the number of red blood cells will be investigated (this is called pharmacodynamics), and it will be investigated to what extent DA-3880 is tolerated. For the purpose of the study the concentration of darbepoetin-* and the possible development of antibodies against darbepoetin-* in your blood will be investigated.

This study will be performed in 60 healthy male/female volunteers, divided over 2 parts, each divided in 2 groups. The first group of each part will be divided in 2 subgroups for the first administration. In each part 2 volunteers will be dosed, one with DA-3880 and one with Aranesp®. After dosing, the safety and tolerability of DA-3880 or Aranesp® will be closely monitored for at least 24 hours. Only if there are no concerns about the safety and tolerability the remaining subjects of the first groups will be dosed.

Study design

The actual study will consist of 2 periods during which you will stay in the clinical research center in Zuidlaren for 8 days (7 nights) followed by 2 days (Day 10 and 13 [Day 1 is the day of administration of study medication]) during which you will visit the clinical research center in Zuidlaren. The time interval between the two administrations is 28 days.

Intervention

During the study the volunteer will receive DA-3880 or Aranesp® after a breakfast, starting 30 minutes before medication administration and which has to be completed before administration of the study medication.

Study burden and risks

The overall risks of DA-3880 administration are considered to be minimal, although some are unforeseeable as the testing of this drug is still at an early stage. As DA-3880 will be administered to humans in this study for the first time, adverse effects in humans have not been reported to date. 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. This means that there is a chance of a minor side effect and a remote chance of something serious happening. It is expected that DA-3880, which is being developed as a copy of Aranesp® and which has an active ingredient similar to Aranesp®, will also likely have the same adverse effects as Aranesp®.

The most common side effects for Aranesp® found in patients are: hypersensitivity reactions, hypertension, rash, redness of the skin, injection site pain, edema, convulsions and stroke. In some cases anti-bodies to Aranesp® caused anemia.

Most of the side effects known for Aranesp® were reported by patients with chronic renal failure or cancer patients receiving chemotherapy, who use the drug for a long period of time. In this study only healthy volunteers will be included, who will receive 2 doses. Therefore it is thought that the probability of the events described below to happen in this study is very low.

The body may recognize DA-3880 and Aranesp® as foreign. As a result an immune response can occur, for example by making antibodies against the study medication. In case teh volunteer would develop in the future symptomatic anemia as a result of chronic renal failure or cancer and that should be treated with one of the medications used in this study, the medication may show less or no effect. This may mean that in such a case, the volunteer may require higher doses of DA-3880 or Aranesp® to overcome these antibodies if still present, or the volunteer would require another medication for his/her treatment.

Procedures: pain, minor bleeding, bruising, possible infection

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 volunteers
18-65 years, inclusive
BMI: 18.0-30.0 kg/m2, inclusive

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 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:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-07-2014
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Aranesp®
Generic name:	darbepoetin-
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	01-07-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-07-2014
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	EUCTR2014-002483-32-NL
CCMO	NL49830.056.14