A randomized, open-label, two-period, two-sequence, single-dose, cross-over study to compare the pharmacokinetics, safety, and tolerability of the auto injector and pre-filled syringe of SB4 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-OMON45442

Source
ToetsingOnline

Brief title
Study comparing PK of SB4 between auto injector and pre-filled syringe.

Condition

- Autoimmune disorders

Synonym
Auto immune diseases

Research involving

Human

Sponsors and support

Primary sponsor: Samsung Bioepis Co., Ltd.
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: Autoimmune diseases, Psoriasis, Rheumatoid arthritis, SB4

Outcome measures

Primary outcome

The primary objective is to demonstrate bioequivalence of the pharmacokinetic

(PK) profiles between SB4 Autoinjector (AI) and SB4 Pre-filled syringe (PFS)

based on AUCinf, AUClast and Cmax in healthy male subjects.

Secondary outcome

The secondary objective is to investigate the safety and tolerability between

SB4 AI and SB4 PFS in healthy male subjects.

Study description

Background summary

SB4 is a compound which is already approved as a drug in the European Union (EU), the Republic of Korea, Canada and Australia for the treatment of several autoimmune diseases including rheumatoid arthritis and psoriasis. In the EU, the trade name for SB4 is Benepali® and in the Republic of Korea, Canada and Australia the trade name for SB4 is Brenzys®. The active substance of SB4 is called *etanercept*. Etanercept is a fusion protein which is produced by joining 2 small pieces of DNA that code for 2 separate human proteins. Etanercept is a compound that is composed of natural proteins and therefore is also called a *biological*.

Autoimmune diseases arise from an abnormal immune response of the body against substances and tissues normally present in the body. The most important characteristic of an autoimmune disease is an inflammation reaction, which can

cause redness, heat, pain, and swelling. SB4 inhibits inflammatory reactions by binding to a certain protein in the body, which decreases the immune response. Specifically, SB4 interferes with the working of a cytokine involved in inflammation, called TNF-* (a cytokine is a small protein involved in the communication between different kinds of cells in the human body).

Study objective

Benepali® and Brenzys® are approved as drugs that are administered as a subcutaneous (under the skin) injection using a pre-filled syringe. With a pre-filled syringe the drug is delivered through a needle which is inserted manually into the skin. The Sponsor has now developed a method to administer SB4 as a subcutaneous injection using an autoinjector. An autoinjector contains a pre filled syringe with a needle which is automatically inserted by pressing the autoinjector against the skin. In this study, SB4 will be administered using both the autoinjector and the pre filled syringe. As such, it can be investigated if the volume of SB4 administered to a volunteer is the same for the two methods of administration.

The main purpose of this study is to compare the pharmacokinetic characteristics of SB4 after subcutaneous injection in the abdomen using an autoinjector and a prefilled syringe. The pharmacokinetics of a compound looks at how the compound gets into the bloodstream, how it is distributed throughout the body, as well as the chemical changes the drug undergoes as it is broken down by the body. It also examines the effects of the breakdown products and how they are passed out of the body.

A second purpose of this study is to test how safe SB4 is and what (if any) side effects are observed when it has been taken.

Finally, the formation of antibodies against SB4 will be investigated.

This study will be conducted in a maximum of 46 healthy male volunteers.

Study design

The actual study will consist of 2 periods (Periods 1 and 2) during each of which the volunteers will stay in the clinical research center for 6 days (5 nights): from the afternoon of Day -1 (1 day before administration of the study compound [Day 1]; also called admission) to the morning of Day 5.

The time interval between dosing in Periods 1 and 2 is 35 days.

Each period they are expected at the clinical research center on Day -1 at 14:00 h in the afternoon. They will be required not to have consumed any food or drinks during the 8 hours prior to arrival in the clinical research center

(with the exception of water).

They will leave the clinical research center on Day 5 of both periods.

After the volunteers have left the clinical research center on Day 5 in each period, they will visit the clinical research center for short ambulatory visits on Days 6, 7, 8, 10, 14 and 21. For the short ambulatory visit on Day 8 and Day 21, they will be required not to have consumed any food or drinks (with the exception of water) during the 8 hours prior to arrival in the clinical research center. There are no food or fluid restrictions prior to arrival for the short ambulatory visits on Days 6, 7, 10 and 14 of both periods. The short ambulatory visit on Day 21 of Period 2 is the follow-up visit for this study; as stated before, prior to the follow-up visit they will be required not to have consumed any food or drinks during the 8 hours prior to arrival in the clinical research center (with the exception of water).

The participation to the entire study, from pre-study screening until the follow-up visit on Day 21 of Period 2, will be a maximum of 84 days.

Intervention

Not applicable.

Study burden and risks

Infections, pain, minor bleedings, bruises and possibly an 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 male subjects
18 - 55 years of age, inclusive
BMI 20.0 - 28.0 kg/m2, inclusive
weight 60.0 - 85.5 kilograms, inclusive
non-smoking

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-04-2017
Enrollment:	46
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Benepali®
Generic name:	n.a.
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	30-01-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-02-2017
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	EUCTR2016-004993-16-NL
CCMO	NL60599.056.17