A Single Dose, Double-Blind, Parallel Arm, Comparative Pharmacokinetic Study of DRL_AB, US licensed Reference Abatacept (Orencia®) and EU approved Reference (Orencia®), Administered by the Intravenous Route to Male Normal Healthy Volunteers

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51534

Source
ToetsingOnline

Brief title
Comparative PK study of DRL_AB, US*licensed and EU-approved Orencia

Condition

- Other condition

Synonym
autoimmune disease, rheumatoid arthritis

Health condition

rheumatoid arthritis

Research involving

Human

Sponsors and support

Primary sponsor: Dr. Reddy□s Laboratories Ltd., Biologics
Source(s) of monetary or material Support: Pharmaceutical Industry

Intervention

Keyword: DRL-Abatacept, Orencia, Rheumatoid Arthritis

Outcome measures

Primary outcome

To demonstrate pharmacokinetic similarity of DRL_AB versus RP and RMP and

between the RP and the RMP after administration of a 750 mg

single IV dose.

Secondary outcome

To assess the safety and tolerability of DRL_AB, RP and RMP.

To assess the immunogenicity of DRL_AB, RP and RMP.

Study description

Background summary

DRL_AB is a new biological product that may potentially be used for the treatment of rheumatoid arthritis (RA). RA is characterized by long-lasting inflammation associated with pain, stiffness, swelling, and sometimes destruction of joints. This results in reduced mobility. RA is an autoimmune disease, which means it is a type of disease where the body*s own immune cells attack the body. DRL_AB is a protein that inhibits the activation of immune cells and could thereby potentially help in the treatment of RA.

Orencia® is a drug that is already approved in Europe and the US for the treatment of RA. The study drug remains in the body for a long time. The half-life, that is the time it takes for the amount of the study drug in the blood to be halved, is approximately 17 days. This is the reason the volunteers have to return to the research center for visits over a long period.

Study objective

The sponsor is developing a biological product (DRL_AB) similar to the approved medicine Orencia®. As part of medical-scientific studies to confirm the similarity of the biological products, the Sponsor wants to compare DRL_AB with EU-approved Orencia® and US-licensed Orencia®. All these 3 biological products have the same active ingredient, called abatacept.

The purpose of this study is to compare how quickly and to what extent DRL_AB, EU-approved Orencia®, and US-licensed Orencia® are available, broken down, and eliminated from the body. In addition, the study will assess the safety and tolerability of DRL_AB and both Orencia® products, and how the body responds to each product.

This is the first study where DRL_AB will be given to humans. It has been extensively tested in the laboratory.Orencia® is no new product; it is already being used by patients for the treatment of rheumatoid arthritis. Please note that when the term *study drug* is used in this document, it can mean DRL_AB, EU-approved Orencia® or US-licensed Orencia®.

Study design

The study lasts a maximum of 16 weeks from the inspection to the follow-up check.

For the research it is necessary to stay in the research center for 6 days (5 nights). After this there are 10 more visits to the research center. These short visits are on Days 6, 8, 10, 15, 22, 29, 43, 57, 71 and 85. Day 1 is the day one receives the study drug. One is expected at the study center on Day -1, which is the day prior to study drug administration. One must be at the research center between 9:30 AM and 2:00 PM. Before coming to the research center, you will be informed about the exact
time. The volunteers leave the study center on Day 5 of the study.

You will receive DRL_AB or EU-approved Orencia® or US-licensed Orencia® as an intravenous infusion (solution of the study drug administered directly into a blood vessel in your arm). The infusion will take 30 minutes and approximately 30 ml of study solution will be administered after it has been diluted with 0.9% sodium chloride

Intervention

Not applicable.

Study burden and risks

Blood draw
Blood draws may hurt or cause bruising. Using an indwelling cannula can sometimes cause inflammation, swelling, hardening of the artery, or blood clotting and bleeding around the puncture site. In some individuals, a blood draw can sometimes cause paleness, nausea, sweating, slow heart rate, or drop in blood pressure with dizziness or fainting.

All in all, we take approximately 181.5 milliliters (ml) of blood from the inspection to the follow-up. This amount does not cause any problems in adults. If the investigator deems this necessary to ensure the safety of the participant, additional samples may be taken for any additional testing. If this happens, the total amount of blood drawn may be more than the amount indicated above.

ECG
To make a heart film, electrodes are placed on the arms, chest and legs. Prolonged use of these electrodes may cause skin irritation.

Coronavirus test
Samples for the coronavirus test will be taken with cotton swabs at the back of the nose and throat. Collecting the samples only takes a few seconds, but can cause discomfort and discomfort. Taking a sample from the back of the throat may result in gagging. When the sample is taken at the back of the nose, you may experience a stinging sensation and the eyes may water.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Healthy Male volunteers, 18 to 50 years of age (both age inclusive) at the time of signing informed consent.
2. In general, good health as determined by a qualified physician based on a comprehensive medical history, physical examination including vital signs, laboratory haematology, clinical chemistry, urinalysis and 12-lead electrocardiogram (ECG) before randomization.
3. Body mass index between 18.5-30.0 kg/m2 (both inclusive) and body weight of 60.0 - 100.0 kg (both inclusive).
4. Screening parameters (vital signs, physical examination, clinical laboratory tests, 12-lead ECG, thyroid function) within the normal range or outside the normal range then assessed as clinically non-significant by the Investigator (unless the value constitutes an explicit exclusion criterion).

Exclusion criteria

1. Positive test result for Quantiferon- TB Gold test, syphilis, hepatitis B, hepatitis C, or HIV-1 or 2.
2. Vaccination with live vaccines within 3 months prior to Screening or intention to receive live vaccines during the trial or up to 3 months after the administration of the study drug. Non-live vaccines should be administered at least a week before the study drug administration to avoid interference with immunization.
3. Any prior exposure to abatacept or to any other agent directly acting on CTLA4 or the CD28-CD80 co-stimulation pathway (eg. pembrolizumab (Keytruda), ipilimumab (Yervoy), nivolumab (Opdivo) and atezolizumab (Tecentriq)) including

investigational products.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	14-06-2022
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Orencia® EU-approved
Generic name:	Abatacept
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Orencia® US-licensed
Generic name:	Abatacept

Ethics review

Approved WMO

Date:	12-04-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	01-06-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-08-2022
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	EUCTR2022-000926-94-NL
CCMO	NL81063.056.22

Study results

Date completed:	09-11-2023
Results posted:	23-05-2024

First publication
03-08-2023