A randomized, parallel-group clinical pharmacology study to assess the pharmacokinetics and pharmacodynamics of Tysabri® in healthy volunteers

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

Summary

ID

NL-OMON46349

Source
ToetsingOnline

Brief title
Tysabri® PK/PD Study

Condition

- Neuromuscular disorders

Synonym
Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: bioeq GmbH
Source(s) of monetary or material Support: Farmeceutische industrie

Intervention

Keyword: Pharmacodynamics, Pharmacokinetics, Pilot

Outcome measures

Primary outcome

Pharmacokinetics and pharmacodynamics

Secondary outcome

N.A

Study description

Background summary

The Sponsor is developing a compound (PB006) similar to Tysabri. In preparation for medical-scientific studies to confirm the similarity of the two compounds, the Sponsor wants to study the effect of different doses of Tysabri on the body.

Tysabri is a drug approved in Europe and the USA for the treatment of Multiple Sclerosis (MS) and in the USA also for the treatment of Crohn*s Disease. MS causes inflammation in the brain that damages the nerve cells. Symptoms of MS can include: walking problems, numbness in the face, arms or legs, problems seeing things, tiredness, feeling off-balance or light headed, bladder and bowel problems, difficulty in thinking and concentrating, depression, acute or chronic pain, sexual problems, and stiffness and muscle spasms.

The active ingredient of Tysabri is natalizumab which is a monoclonal antibody. These antibodies work by binding to proteins in the body so that the harmful effect of that protein is removed. Tysabri stops the cells that cause inflammation from going into the brain. This reduces nerve damage caused by MS.

The study will be performed in up to 36 volunteers who will participate in 16 visits, of which one will be a confinement of 4 days.

Study objective

The purpose of this study is to investigate how quickly and to what extent different doses of EUapproved Tysabri® are absorbed and eliminated from the body (this is called pharmacokinetics) and how the body responds to different doses of Tysabri (this is called pharmacodynamics) and. In addition, the study will assess the safety profile of Tysabri at different doses.

Study design

The actual study will consist of 1 period during in which the volunteer will stay in the research center in Groningen location UMCG for 4 days (3 nights). Day 1 is the day of administration of the study compound. The volunteer is expected at the research center at 14:00 h in the afternoon prior to the day of administration of the study compound. The volunteer will leave the research center on Day 3 of the study.This will be followed by 11 days during which the volunteer will visit the research center for a short visit. These short visits will take place on Day 5, 8, 15, 22, 29, 36, 43, 57, 71, 78, and 85.

During the volunteers last short visit (Day 85) their health will be checked for the last time. An additional follow-up visit is planned between Day 162 and 176 to monitor for any signs or symptoms that may indicate progressive multifocal leukoencephalopathy (PML).

Intervention

Tysabri will be given as an intravenous infusion (solution of the compound that will be administered directly in a blood vessel) over 60 minutes. The volunteer will receive one of 3 doses of Tysabri (1, 3, or 6 mg/kg body weight).

Study burden and risks

The following side effects have been reported in medical-research studies: urinary tract infection, sore throat and runny or blocked up nose, shivering, itchy rash (hives), headache, dizziness, feeling sick (nausea), being sick (vomiting), joint pain, fever, tiredness.

Drawing blood and insertion of the indwelling cannula may be painful or cause some bruising.A small amount of blood will be drawn during the screening.

To monitor your heart rate, electrodes (small, plastic patches) will be pasted at specific locations on the chest and abdomen. Prolonged use of these electrodes can cause skin irritation (rash and itching).

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 males and females.
18-65 years, inclusive, at screening.
BMI: 18.5-32.0 kg/m2.
Weight: 50.0-110.0 kg.

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. Presence of JCV antibodies. In case of participation in another drug study within 90 days before the start of this study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-03-2018
Enrollment:	18
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tysabri®
Generic name:	n.v.t.
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	05-03-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	15-03-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	26-04-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-04-2018
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	EUCTR2018□000199□13-NL
CCMO	NL65133.056.18