A study to assess the safety, tolerability and pharmacokinetic properties of CEP-37248, a drug for the treatment of autoimmune inflammatory diseases, in healthy men.

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

Summary

ID

NL-OMON40424

Source
ToetsingOnline

Brief title
CEP-37248 SAD Study

Condition

- Autoimmune disorders

Synonym
Autoimmune disease

Research involving
Human

Sponsors and support

Primary sponsor: TEVA Pharma
Source(s) of monetary or material Support: Farmaceutische Industrie

Intervention

Keyword: Autoimmune inflammatory diseases, CEP-37248, Healthy men

Outcome measures

Primary outcome

Safety, Tollerability

Secondary outcome

PK

Study description

Background summary

CEP-37248 is a new investigational compound that may eventually be used for the treatment of autoimmune inflammatory diseases. Examples of autoimmune inflammatory diseases are ulcerative colitis and Crohn*s disease, inflammatory diseases of the intestine. CEP-37248 is a monoclonal antibody against two proteins that are naturally found in the body, IL-12 and IL-23 (IL stands for interleukin). Both proteins play a role in inflammation. CEP-37248 may prevent IL-12/IL-23 function. As a result, inflammatory reactions are decreased. This is the first time that this compound is being given to humans.

Study objective

The purpose of the study is to investigate to what extent CEP-37248 is tolerated.
Also investigated is how quickly and to what extent CEP-37248 is processed by the body (PK). In addition, the effect of the compound on how much IL-12 and IL-23 is in the body and effects on the immune system will be investigated (PD).

Study design

This study will be performed in 85 healthy male volunteers, divided into 9

groups. The study will be performed in each group separately; the groups will start in the order in which they have been numbered. Group 1 will consist of 9 volunteers, Groups 6 and 8 will consist of 14 volunteers and all other groups (Groups 2 to 5, Group 7 and Group 9) will consist of 8 volunteers.

Intervention

CEP-37248

Study burden and risks

As CEP-37248 will be administered to humans for the first time in this study, adverse effects of CEP-37248 in humans have not been reported to date. However, CEP-37248 has been studied in animals. In monkeys the drug was well-tolerated and no adverse events were observed. No CEP-37248-related adverse effects were seen up to the highest dose tested. Another similar drug, Stelara® or ustekinumab * which is also a monoclonal antibody- is currently approved and used by psoriasis patients. Since ustekinumab and CEP-37248 slow down the activity of the immune system you may be more susceptible to infections. The most common adverse reactions seen with ustekinumab are infections of the breathing system and nasopharyngitis (common colds). These adverse effects are generally mild. In case of subcutaneous administration a local reaction at the site of the injection may occur. Any drug can cause allergic reactions; true allergic reactions are unlikely since you will not have been previously exposed to the drug or a similar drug. Hypersensitivity can occur during intravenous administration.

Contacts

Public
TEVA Pharma

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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
18 -45 years
BMI of 18.0 to 30.0 kg/m2
Weight at least 50 kg

Exclusion criteria

Suffering from: hepatitis B, 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 90 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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-08-2013
Enrollment:	93
Type:	Actual

Ethics review

Approved WMO Date:	31-07-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-08-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-02-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-02-2014
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	EUCTR2013-002587-61-NL
CCMO	NL45784.056.13