A randomized, double-blind, placebo-controlled, single and multiple ascending dose study to evaluate the safety, tolerability, pharmacokinetics and food effect of orally administered LYC-30937 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-OMON41886

Source
ToetsingOnline

Brief title
LYC-30937 SAD MAD FE Study

Condition

- Autoimmune disorders

Synonym
colitis ulcerosa, Inflammatory bowel disease

Research involving

Human

Sponsors and support

Primary sponsor: Lycera Corp.
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: First in Men study, food effect, pharmacokinetics, safety, tolerability, ulcerative colitis

Outcome measures

Primary outcome

- Safety an tolerability: adverse events, vital signs including body

temperature, ECG-parameters, continuous lead II electrocardiogram monitoring,

laboratory parameters, physical examination.

- Pharmacokinetic parameters

- Food effect.

Secondary outcome

na

Study description

Background summary

LYC-30937 is a new investigational compound that may eventually be used for the treatment of ulcerative colitis, which is a form of inflammatory bowel disease (IBD). Ulcerative colitis is a condition that causes chronic inflammation and ulceration of the lining (mucosa) of the large intestine. This condition is commonly treated with medication to suppress local inflammation (5-aminosalicylic acid [5-ASA] drugs, or corticosteroids) or the entire immune system (immunosuppressants), which are both known to have many side effects. The new investigational compound LYC-30937 affects a specific enzyme (ATPase), which is involved in the energy supply to a subset of white blood cells that facilitate the disease. This is the first time that LYC-30937 is being given to

humans.

Study objective

The purpose of the study is to investigate the safety of LYC-30937 and to what extent LYC-30937 is tolerated. It will also investigate how quickly and to what extent LYC-30937 is absorbed and eliminated from the body (this is called pharmacokinetics). Furthermore the effect of food on the pharmacokinetics of LYC-30937 will be investigated.

Study design

Study design:
Part A: single asending doses
Part B: multiple ascending doses
Part C: food-effect part

Intervention

na

Study burden and risks

Procedures: pain, light bleeding, haematoma, possibly an infection

In Part A of the study, a total of 33 healthy volunteers received a single dose of LYC 30937 or placebo at a dose of 2 to 300 mg. Only few adverse events were reported by these volunteers and they were all of mild intensity. Six volunteers reported adverse events which were considered to be possibly related to LYC 30937. One of these volunteers reported a hot feeling and the remaining adverse events were related to the gastro-intestinal tract, including flatulence (reported by 2 volunteers), abdominal pain, loose stools and diarrhea. At this moment it is unknown whether the latter adverse events were reported by volunteers receiving LYC 30937 or placebo.

When LYC 30937 was administered daily to monkeys at doses of 3 to 30 mg/kg for 28 days, no adverse events were observed at the lowest dose level (3 mg/kg). The most frequently observed adverse events at doses of 10 or 30 mg/kg included vomiting, reduced appetite, bristling hair, pale skin, hunched posture, drooping of the eyelid, weakness, abdominal swelling, decreased activity, reduced body temperature, diarrhea and dehydration. In addition, some transient changes in blood components and liver enzymes were noted. Of the 12 monkeys who received the highest dose, one animal was killed after 16 days and 3 animals were killed after 19 days because of a deteriorating condition. The remaining animals completed the study.

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

Age: 18-45 years
Gender: Male
BMI: 18.0-32.0 kg/m2

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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2015
Enrollment:	101
Type:	Actual

Ethics review

Approved WMO Date:	13-03-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-03-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-09-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	08-09-2015
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	EUCTR2014-000347-32-NL
CCMO	NL48401.056.14