A STUDY OF THE SAFETY, TOLERABILITY, PHARMACOKINETICS AND PHARMACODYNAMICS OF LY3045697 AFTER SINGLE ORAL DOSING IN HEALTHY SUBJECTS

Published: 19-12-2012
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Primary : To evaluate the safety and tolerability of single oral doses of LY3045697 administered to healthy subjects Secondary : To investigate the pharmacokinetics of single oral doses of LY3045697 administered to healthy subjects Exploratory : To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON38917

Source
ToetsingOnline

Brief title
ASEA

Condition

- Renal disorders (excl nephropathies)

Synonym
Chronic kidney disease, Kidney Disease

Research involving
Human

Sponsors and support

Primary sponsor: Chorus, Eli Lilly and company
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: LY3045697, PK, Safety, Single rising dose

Outcome measures

Primary outcome

Safety and tollerability of LY3045697

Secondary outcome

Pharmacokinetics of LY3045697

Study description

Background summary

LY3045697 is a new investigational compound that may eventually be used for the treatment of chronic kidney disease (CKD). LY3045697 is not registered as a drug. This is the first time that this compound is being given to humans. This study is necessary for the further development of LY3045697.

Study objective

Primary : To evaluate the safety and tolerability of single oral doses of LY3045697 administered to healthy subjects
Secondary : To investigate the pharmacokinetics of single oral doses of LY3045697 administered to healthy subjects
Exploratory : To explore the effect of LY3045697 on sodium and potassium renal handling
: To explore the pharmacodynamic effects on aldosterone, cortisol and their steroidogenic precursors (e.g. 11-deoxycortisol, 11-deoxycorticosterone, corticosterone) after single dose administration of LY3045697 in healthy subjects

Study design

This is a randomized, double blind, placebo-controlled, dose escalating,

incomplete cross-over design study in healthy males and females of non-child bearing potential in 2 groups of 9 subjects (6 subjects on active and 3 on placebo) each. Groups 1 and 2 will be dosed in an alternating fashion during 3 separate admission periods. The 3rd group will be dosed in two consecutive periods. There will be a wash-out period of at least 5 days between dose levels for an individual subject. Dosing will be in the fed state. Subjects will receive placebo in one period only.

Intervention

Single oral dose of LY3045697 or placebo

Study burden and risks

As LY3045697 will be administered to humans for the first time in this study, no adverse effects have been reported to date. Animal studies showed that LY3045697 was well tolerated in rats for 28 days at very high doses (1000 mg/kg). In monkeys this was the case for doses of 30 mg/kg. In both species there was a slight increase in weight and volume of the liver and adrenal glands.

LY3045697 may reduce blood aldosterone levels. LY3045697 may cause increased potassium levels which could cause abnormal heart rhythm. LY3045697 may also cause blood pressure to drop. LY3045697 may also reduce blood cortisol levels. Lack of cortisol may result in abdomen pain, nausea and vomiting, muscles aches, loss of appetite and weight, lack of energy and a low blood pressure. LY3045697 may reduce the amount of sodium in your blood. Subjects may also experience increased urination.

Contacts

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Chorus, Eli Lilly and company

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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 or females (postmenopausal or surgically sterile)
-Postmenopausal female subjects must be between the ages of 45 and 65 years, inclusive
-Male subjects and surgically sterile females must be between the ages of 18 and 65 years, inclusive
-BMI between 18.0 and 32.5 kg/m2 , inclusive

Exclusion criteria

Suffering from hepatitis B, hepatitis C, 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 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):	10-01-2013
Enrollment:	27
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-12-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-05-2013
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-05-2013
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	EUCTR2012-004968-22-NL
CCMO	NL42881.056.12