Study of the Safety, Tolerability and Pharmacokinetics of LY2623091 after Single Oral Dosing in Healthy Subjects

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Primary objective:- to investigate the safety and tolerability after a single oral dose in healthy men and women of non-childbearing potential. Secondary objective:- to investigate the pharmacokinetic of a single oral dose in healthy men and women...

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

Summary

ID

NL-OMON34283

Source
ToetsingOnline

Brief title
LY2623091 SAD study

Condition

- Renal disorders (excl nephropathies)

Synonym
chronic kidney disease, Kidney failure

Research involving
Human

Sponsors and support

Primary sponsor: Chorus LRL (Division of Eli Lilly)
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Kidney disease, LY2623091, SAD

Outcome measures

Primary outcome

Pharmacokinetics

Safety

Secondary outcome

n.a.

Study description

Background summary

The drug to be given is a new, investigational compound that may eventually be used for the treatment of chronic kidney disease. This compound is in the development phase. Chronic kidney disease is characterized by ongoing deterioration of kidney function. Ultimately, total loss of kidney function may occur, requiring patients to use dialysis or renal transplant to survive. Current treatments do not counter the deterioration of kidney function sufficiently. Consequently, new therapies are urgently needed for these patients. The experimental drug used in this study is being developed to safely improve kidney fuction in chronic kidney disease patients, using a novel mechanism.

Study objective

Primary objective:
- to investigate the safety and tolerability after a single oral dose in healthy men and women of non-childbearing potential.

Secondary objective:
- to investigate the pharmacokinetic of a single oral dose in healthy men and women of non-childbearing potential.

Study design

Design:

This study is a randomized, double-blind, placebo-controlled, dose escalating, incomplete cross-over study. Two cohorts of 9 healthy men and women of nonchildbearing potential are planned for inclusion in this study. The cohorts will be dosed alternatively in the course of a dose escalation with the proposed dose escalation scheme: 5 mg, 15 mg, 50 mg, 150 mg, 450 mg, and 900 mg. The 3-period dosing schedule will be separated by a washout period of at least 7 days. A follow-up visit will take place 7-10 days after the last dose for each subject.

Procedures and assessments:
Screening and follow-up: clinical laboratory (including aPTT at screening), physical examination, 12-lead ECG (in triplicate at screening), vital signs (including temperature and respiratory rate at screening); at eligibility screening: medical history, drug screen, HBsAg, anti HCV, anti-HIV 1/2; to be repeated upon admission: weight, abbreviated physical examination, urine alcohol and drug screen.

Observation period:
Three periods in clinic from -17 h up to 72 h after drug administration on Day 1.

Blood sampling:
For pharmacokinetics in plasma: pre-dose and 0.5, 1, 2, 3, 4, 6, 8, 12, 24, 48 and 72 hours post-dose and at follow-up visit
For pharmacogenomics: pre-dose on Day 1.

Safety assessments:
Adverse events: throughout the study; ECG (in triplicate) and vital signs: pre-dose (including temperature and respiratory rate) and 1, 3, 6 and 24 h post-dose; clinical laboratory: pre-dose (including aPTT) and 24 (including aPTT) and 72 h post-dose.

Bioanalysis:
Analysis of plasma LY2623091 samples using a validated LC/MS method by Sponsor

Intervention

Active substance: LY2623091

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection.

Contacts

Public
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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 men and women ((postmenopausal/sterilized)
- 18 - 65 years of age, inclusive;
- BMI < 32.5 kg/m2;
- Non smoking or smoking lesss than 10 cigarettes/day

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2010
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	06-07-2010
Application type:	First submission
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	EUCTR2010-021213-23-NL
CCMO	NL32960.056.10