Study of the safety, tolerability, pharmacokinetics and pharmacodynamics of multiple oral dosing in healthy subjects including brain Serotonin Transporter (SERT) occupancy by Positron Emission Tomography (PET).

Published: 18-05-2010
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Primary:- to evaluate the safety and tolerability of the compound in different multiple dosing regimens in healthy subjects in different dosing regimensSecondary:- to characterize the pharmacokinetics of multiple oral doses of LY2878735 administered...

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

Summary

ID

NL-OMON34068

Source
ToetsingOnline

Brief title
MAD/PET study

Condition

- Other condition

Synonym
visceral pain

Health condition

chronische pijn aan beschadigde organen.

Research involving
Human

Sponsors and support

Primary sponsor: Eli Lilly
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: Visceral pain syndromes

Outcome measures

Primary outcome

Pharmacodynamics, 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 pain that is caused by damaged or injured internal organs (visceral pain). Visceral pain is by far, the most common form of pain.
Few drugs have been approved for specific visceral pain conditions, and current therapies offer limited efficacy.
The compound is a potent and selective serotonine/norepinephrine (5-HT/NE) reuptake inhibitor (SNRI). SNRIs are utilized in the treatment of depression and chronic pain. SNRIs increase the levels of both serotonin and norepinephrine by inhibiting their reabsorption (reuptake) into the cells in the brain. Serotonin and norepinephrine are both known to play an important part in mood. Elevation of norepinephrine is thought to be necessary to be effective against pain as well.

Study objective

Primary:
- to evaluate the safety and tolerability of the compound in different multiple dosing regimens in healthy subjects in different dosing regimens

Secondary:
- to characterize the pharmacokinetics of multiple oral doses of LY2878735 administered to healthy subjects in different dosing regimens
- to evaluate the effect of LY2878735 on the change from baseline in plasma concentrations of norepinephrine and its metabolite dihydroxyphenylglycol as an indirect measure of norepinephrine activity
- to evaluate the effect of LY2878735 on the change from baseline in ex vivo norepinephrine/serotonin uptake inhibition
- to explore the relationship between dose/exposure of LY2878735 and brain serotonin receptor transporter (SERT) occupancy after multiple oral doses in healthy subjects by direct measurement with Positron Emission Tomography (PET) using 11C-DASB ligand

Study design

Part A:
A randomized, double-blind, placebo-controlled, multiple-ascending dose study.

Part B:
An open-label PET study.

Part C (optional):
A randomized, double-blind, placebo-controlled, multiple-ascending dose study.

Intervention

Active substance: LY2878735

Study burden and risks

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

Contacts

Public
Eli Lilly

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Indianapolis, 46285
United States of America
Scientific
Eli Lilly

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United States of America

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy male or female (post-menopausal or surgically sterile), age between18 and 65 years, BMI between 19 and 32.5 kg/m2, non-smoker or light to moderate smoker, at screening state of healthy must satisfy the entry requirements.;Addition Part B:
Non-exposure to any radiation for diagnostic reasons during work or during participation in a medical trial in the past year, non claustrophobic.

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 (for men)/1.0 liters (for women) 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):	25-05-2010
Enrollment:	51
Type:	Actual

Ethics review

Approved WMO Date:	18-05-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-05-2010
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	EUCTR2010-020231-39-NL
Other	n.a.
CCMO	NL32452.056.10