A FIRST-IN-HUMAN SINGLE-DOSE ESCALATION STUDY OF THE SAFETY AND PHARMACOLOGY OF LY2165766 INCLUDING BRAIN DOPAMINE D2 RECEPTOR OCCUPANCY BY POSITRON EMISSION TOMOGRAPHY (PET)

Published: 04-09-2008
Last updated: 06-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON33530

Source
ToetsingOnline

Brief title
LY2165766 SDSS/PET study

Condition

- Schizophrenia and other psychotic disorders

Synonym
schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Chorus LRL (devisie van Eli Lilly)
Source(s) of monetary or material Support: sponsor van dit onderzoek

Intervention

Keyword: LY2165766, schizophrenia

Outcome measures

Primary outcome

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Secondary outcome

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Study description

Background summary

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Study objective

zie hierboven

Study design

zie hierboven

Intervention

zie hierboven

Study burden and risks

zie hierboven

Contacts

Public
Chorus LRL (devisie van Eli Lilly)

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Scientific
Chorus LRL (devisie van Eli Lilly)

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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 male
Part A: 18 - 65 year.
Part B: 35 - 65 year
Part C: 35 - 65 year

Exclusion criteria

Relevant disease in medical history

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):	12-10-2008
Enrollment:	38
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[11C] Raclopride
Generic name:	nvt
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	04-09-2008
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-09-2008
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	16-03-2009
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-03-2009
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-04-2009
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-04-2009
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	EUCTR2008-005287-14-NL

Register	ID
CCMO	NL24758.056.08