A Phase I, open label trial in healthy subjects to evaluate the central nervous receptor occupancy of pipamperone at the 5-HT2A and D2 receptor by means of Positron Emission Tomography.

Published: 15-12-2009
Last updated: 04-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON34843

Source
ToetsingOnline

Brief title
Pipamperone PET study

Condition

- Mood disorders and disturbances NEC

Synonym
depression, major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: PharmaNeuroBoost NV

Source(s) of monetary or material Support: PharmaNeuroBoost

Intervention

Keyword: PET, Pipamperone, receptor occupancy

Outcome measures

Primary outcome

-

Secondary outcome

-

Study description

Background summary

-

Study objective

-

Study design

-

Intervention

-

Study burden and risks

-

Contacts

Public

PharmaNeuroBoost NV

Alkerstraat 30 A
3570 Alken
Belgium
Scientific
PharmaNeuroBoost NV

Alkerstraat 30 A
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Belgium

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy males and females
Between 35 and 75 years of age

Exclusion criteria

Clinical significant abnormalities for medical examination

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-12-2009
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dipiperon
Generic name:	Pipamperone
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	not applicable
Generic name:	pipamperone

Ethics review

Approved WMO

Date:	15-12-2009
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	21-12-2009
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	17-02-2010
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-02-2010
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	EUCTR2009-012699-28-NL
CCMO	NL30815.056.09