An open label dose-ranging study in healthy male subjects to investigate the binding potential of JNJ-40411813 to serotonin 2A receptors in the central nervous system.

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In this study, the binding of JNJ-40411813 to the brain cells and the concentration of JNJ-40411813 in the blood will be studied. Furthermore, the safety and tolerability of JNJ-40411813 will be investigated upon administration of JNJ-40411813,...

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

Summary

ID

NL-OMON36262

Source
ToetsingOnline

Brief title
Protocol 40411813EDI1008

Condition

- Schizophrenia and other psychotic disorders

Synonym
mental disorder, psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: Johnson & Johnson

Intervention

Keyword: healthy male subjects, Open label, PET

Outcome measures

Primary outcome

To estimate the plasma concentration associated with 50% 5-HT2A binding.

To determine the 5-HT2A binding within the maximal feasible dose range.

To investigate if there is a change in plasma concentration-occupancy relation

over time.

To investigate the safety and tolerability of JNJ-40411813 in healthy male

subjects.

Secondary outcome

Not applicable.

Study description

Background summary

JNJ-40411813 (study medication) is a new drug currently being developed for the treatment of schizophrenia and other disorders of the central nervous systems (CNS).

Study objective

In this study, the binding of JNJ-40411813 to the brain cells and the concentration of JNJ-40411813 in the blood will be studied. Furthermore, the safety and tolerability of JNJ-40411813 will be investigated upon administration of JNJ-40411813, single dose.

Study design

An open label flexible dose study in healthy male subjects to investigate the binding potential of JNJ-40411813 to serotonin 2A receptors in the central nervous system.

Intervention

The study medication will be given once on Day 1. The blood samples, vital signs and ECG will done at screening, in the clinic and at the follow-up. Furthermore a [11C]-MDL100,907 PET scan will be done twice per subject during screening and on Day 1. Furthermore a MRI scan will be done at screening per subject.

Study burden and risks

This is the 7th study with JNJ-40411813. The following side-effects were observed for subjects who received a single dose of JNJ-40411813:
- CNS (central nervous system)-related side effects: Headache, dizziness, sedation, euphoria (feeling very happy), fatigue, and blurred vision
- Gastrointestinal side effects: nausea, loose stools, and vomiting,
- Other: syncope (fainting), postural hypotension (drop in blood pressure when standing up).

All of the mentioned side effects were mild to moderate (i.e. did not severely affect daily functioning) and reversible. There were no serious adverse events in that study and no treatment related changes were observed relating to blood values, ECG, vital signs or physical examinations. No new adverse event was observed in the subsequent single dose studies.

The adverse event profile of multiple dose studies with JNJ-40411813 was generally consistent with that expected based on results of single-dose data. The most common treatment-emergent adverse events were dizziness, fatigue and headache. All adverse events were of mild or moderate severity. Moderate adverse events observed in subjects receiving JNJ 40411813 included dizziness (7 subjects), dyspepsia (1 subject), and blood triglycerides increased (1 subject).

Before JNJ-40411813 was given to humans for the first time, it has been extensively tested in animals, according to regulatory guidelines. Based on the data from the animal studies, no other side effects are expected than those already reported with the planned doses in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Male
Age between 18-45 (inclusive)
BMI between 18 and 30 kg/m^2 (inclusive)

Exclusion criteria

Clinical significant abnormalities during medical research

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):	29-10-2010
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	JNJ-40411813
Generic name:	JNJ-40411813

Ethics review

Approved WMO Date:	27-10-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-11-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-11-2010
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-01-2011
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-02-2011
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	EUCTR2010-022176-32-NL
CCMO	NL34190.056.10