An Open-Label, Single Dose Study to Investigate Striatal Dopamine D2 Receptor Binding of JNJ-37822681 Using [11C]Raclopride Positron Emission Tomography in Healthy Male Subjects

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

Summary

ID

NL-OMON30989

Source
ToetsingOnline

Brief title
PET study

Condition

- Schizophrenia and other psychotic disorders

Synonym
schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Johnson & Johnson Pharmaceutical
Source(s) of monetary or material Support: Sponsor

Intervention

Keyword: Dopamine D2 receptor binding, PET scan, safety, tolerability

Outcome measures

Primary outcome

Dopamine D2 receptor binding is measured and the relation between the

pharmacokintetics of JNJ-37822681 and the receptor binding is determined.

safety and tolerability, adverse events, changes in blood pressure, pulse rate,

lab. safety data, 12-lead ECG and physical examination and also studied.

Secondary outcome

n.a.p.

Study description

Background summary

JNJ-37822681 is a selective, fast-dissociating, dopamine D2 antagonist for the treatment of psychosis. Because the compound is selective and fast dissociating, it is expected that treatment with JNJ 37822681 will result in less side effects than those experienced with currently marketed therapies. JNJ-37822681 is hypothesized to have clinical effects through interactions with the dopamine D2 receptor. In this study, [11C]raclopride PET will be used to directly investigate the interaction of JNJ-37822681 with striatal dopamine D2 receptors. Understanding the relationship between plasma concentrations and occupancy will support rational dose selection for Phase II efficacy studies in patients with schizophrenia.

Study objective

The objective of this study is to investigate the relationship between JNJ-37822681 plasma concentration and striatal dopamine D2 receptor occupancy

in healthy male subjects.
The secondary objective of this study is to investigate the safety and tolerability of JNJ-37822681 in healthy male subjects.

Study design

This is an open label, randomized study. 8 subjects are planned to participate in this study. Each subject will receive 2 dose levels of JNJ-37822681 and 3 [11C]raclopride PET scans.

During the screening subjects will be checked for eligibility. Subjects who are eligible to participate in the study will have an MR scan and the baseline PET scan.

The volunteerd will be admitted to the study unit in the afternoon of Day -1. On Day 1 the subjects will be taken to the PET centre of the VUMC and they will receive the study medication followed by a PET scan approximately 2 hours later. The subjects will then be taken back to the study unit. Subjects will be released in the morning of Day 2.

Subjects 1 and 2 will receive a single oral dose of 10 mg JNJ-37822681. Further dose levels will be determined based on the results obtained from previous subjects, and on tolerability/safety observations from parallel ongoing single and multiple dose studies. If appropriate, > 1 measurements may be made at 1 dose level.

Intervention

Each subject will receive 2 dose levels of JNJ-37822681 and 3 [11C]raclopride PET scans.

Study burden and risks

The associated risks are the occurence of possible side effects of the use of JNJ-37822681.
The burden of the subjects are the confinement period in the unit, venapuncture, and the insertion of the canula.

All subjects will receive 3 PET scans. The total radiation is 6 mSv, which is largely within the legal limits.

All subjects will be carefully monitored for possible adverse events by experienced study personnel and physicians

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

healthy male subjects between 18 - 55 years of age
BMI between 18 and 30 kg/m²

Exclusion criteria

History of, or currently active, significant illness or medical disorder
Yearly cumulative dose due to exposure to radiation above 10 mSv
Any significant MR abnormalities as determined by a neuroradiologist
Metal implants
Claustrophobia
History of epilepsy or fits or unexplained black-outs

Significant history of or current psychiatric or neurological disease

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2007
Enrollment:	8
Type:	Anticipated

Ethics review

Approved WMO Date:	07-08-2007
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-10-2007
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-01-2008
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2007-004077-26-NL
CCMO	NL19020.029.07