A Blinded, Placebo-Controlled, Randomized, Single Ascending Dose Study in Healthy Male Subjects to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of JNJ-37822681

Published: 27-04-2007
Last updated: 08-05-2024

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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-OMON30850

Source
ToetsingOnline

Brief title
N/A

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychosis

Research involving

Human

Sponsors and support

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

Intervention

Keyword: dose escalation, pharmacodynamics, pharmacokinetics, safety

Outcome measures

Primary outcome

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

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

pharmacokinetic blood and urine tests

pharmacodynamic evaluations: prolactine concentration, adaptive tracking,

Saccadic eye movements, smooth pursuit eye movement test, Bond and Lader VAS,

Bowden VAS, body sway, tapping, and pEEG.

Secondary outcome

N/A

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.

Study objective

The objectives for the study are:
to investigate the safety and tolerability of JNJ-37822681 following single

dose administrations in healthy male subjects.
to investigate the plasma pharmacokinetic profile of JNJ-37822681 and metabolites after single ascending dose administration
to investigate renal excretion of JNJ-37822681
·to investigate the pharmacodynamic effect of JNJ-37822681 (specifically: effect on prolactine (PRL) concentrations, saccadic eye movements, smooth pursuit eye movements, adaptive tracking, Bond and Lader Visual Analogue Scales, Bowdle VAS, body sway, tapping, and pharmacoelectroencephalogram (pEEG).

Study design

This is an alternating panel, randomized, blinded, placebo-controlled study in healthy male subjects. Two panels of each 12 subjects will participate in the study. Each subject will receive 3 doses of JNJ 37822681 and 1 placebo dose, randomized over 4 study periods. Panels will alternate. At each dosing occasion 9 subjects will receive JNJ-37822681 and 3 placebo. It is planned that subjects will receive escalating doses of JNJ-37822681.

At periods 1 - 3 subjects will be admitted to the study unit in the morning of Day -1. On Day 1 the study medication will be administered and the subjects will be discharged on Day 3. In period 4 the subjects will be discharged on Day 4, 72 hours after the study medication administration.

Doses will be escalated only if acceptable safety and tolerability was demonstrated at the preceding, lower, dose level. Selected pharmacokinetic and pharmacodynamic endpoints will also be generated following each dose administration and will be available to support dose escalation in the same subject. If peak concentration-related dose-limiting side effects are observed, it may be decided to administer the same dose but divided over multiple administrations during Day 1 for the next period.

Intervention

Each subject will receive 3 doses of JNJ-37822681 and 1 placebo dose, randomized over 4 study periods. It is planned that the subjects will receive escalating doses of JNJ-37822681. The starting dose will be 0,5 mg JNJ-37822681

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 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
History of epilepsy or fits or unexplained black-outs

Significant history of or current neurological disease

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):	31-05-2007
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	27-04-2007
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	24-07-2007
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2007-001301-21-NL
CCMO	NL17271.058.07