An open-label, fixed-sequence study in healthy male subjects to assess the effect of single and multiple-doses of JNJ-54861911 on the components of a Drug *Cocktail* representative for CYP3A4, CYP2C9, and CYP1A2 substrates.

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- To assess the effects of single and multiple daily doses of 50 mg JNJ-54861911 once daily (q.d.) on the pharmacokinetics of caffeine, midazolam, and tolbutamide in healthy male subjects. - To assess the safety and tolerability of the concomitant...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41185

Source
ToetsingOnline

Brief title
54861911ALZ1010 (CS0221)

Condition

- Other condition

Synonym
Early Alzheimer's Disease

Health condition

Nervous System Diseases - nervous system disorder (Alzheimer's disease)

Research involving
Human

Sponsors and support

Primary sponsor: QPS Netherlands B.V.
Source(s) of monetary or material Support: Janssen Research & Development

Intervention

Keyword: fixed-sequence, open-label, single and multiple-doses

Outcome measures

Primary outcome

Phamacokinetics

Safety

Tolerability

Secondary outcome

N.A.

Study description

Background summary

The purpose of this study is to find out what effect JNJ-54861911 has on the combination of caffeine, midazolam and tolbutamide. Another purpose is to find out if JNJ-54861911 can cause side effects (unexpected or unwanted reactions from taking a drug) when it is given together with caffeine, midazolam and tolbutamide.

Study objective

- To assess the effects of single and multiple daily doses of 50 mg JNJ-54861911

once daily (q.d.) on the pharmacokinetics of caffeine, midazolam, and tolbutamide in healthy male subjects.
- To assess the safety and tolerability of the concomitant use of JNJ-54861911
q.d. with caffeine, midazolam, and tolbutamide.

Study design

This is an Open-Label, Fixed-Sequence Study in Healthy Male Subjects to Assess the Effect of Single and Multiple-Doses of JNJ-54861911 on the Components of a Drug *Cocktail* Representative for CYP3A4, CYP2C9, and CYP1A2 Substrates.

Intervention

- Review of medical history
- Review of medications
- Physical exam (including height and body weight)
- Vital signs: supine and standing blood pressure, pulse rate and oral temperature.
- ECG
- Urine sampling
- Alcohol breath test
- Monitoring for hypoglycemia
- Blood draw: needle or a cannula, a total of about 306 mL will be drawn during the entire study
- Questions regardiing general health.

Study burden and risks

The risk is small. The patients will be closely monitored. The patients will be regularly questioned for any side effects and safety tests are scheduled (vital signs). The patients will be asked to report, as soon aspossible, any changes in physical and/or mental well being.

The blood collection procedure is not dangerous, but may cause discomfort or bruising. Occasionally, fainting or an infection at the blood sampling site may occur.

Shaving may be required for proper placemant of ECGpatches. This may cause irritation or bleeding of the skin.

ECG patches may cause redness, itching, rash, or blisters on the skin and/or hair loss due to removal of ECG patches.

Contacts

Public
QPS Netherlands B.V.

Petrus Campussingel 123
Groningen 9713 AG
NL
Scientific
QPS Netherlands B.V.

Petrus Campussingel 123
Groningen 9713 AG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Subject must be a man, 18 to 55 years of age, inclusive.
2. Subjects must have a body mass index (BMI) between 18 and 30 kg/m2, inclusive (BMI = weight/height^2) and a body weight of not less than 50 kg.
3. Subject must be healthy on the basis of physical examination, medical history, vital signs, and 12-lead ECG performed at screening or admission (up to Day 1 predose). Minor deviations in ECG, which are not considered to be of clinical significance to the investigator, are acceptable.

Exclusion criteria

1. Subject has any clinically significant abnormal findings in physical examination, vital signs or 12-lead ECG (incl. QTcF>450msec, Left Bundle Branch Block, AV Block second degree or higher, permanent pacemaker or implantable cardioverter defibrillator (ICD)) at screening or admission (up to Day 1 predose), which in the opinion of the investigator are not appropriate and reasonable for the population under study.
2. Subject has a history of or current liver or renal insufficiency; closedangle glaucoma, significant cardiac, vascular, pulmonary, gastrointestinal, endocrine (e.g. thyroid disease, diabetis mellitus), neurologic, hematologic, rheumatologic, psychiatric, or metabolic disturbances.
3. Subject has a history of epilepsy or fits or unexplained black-outs other than vasovagal collapse.
4. Subject has a known history of glucose-6-phopshate dehydrogenase deficiency (G6PD) deficiency (favism)
5. Subject has known allergies, hypersensitivity, or intolerance to JNJ-54861911 or its excipients (refer to IB), sulfonamides, midazolam, caffeine or tolbutamide.
6. Subject has contraindications to the use of caffeine, midazolam or tolbutamide per local prescribing information.
7. Subject has had major surgery, (e.g., requiring general anesthesia) within 8 weeks before screening, or will not have fully recovered from surgery.

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):	06-10-2014

Enrollment:	16
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	-
Generic name:	Caffeine monohydrate
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	-
Generic name:	JNJ-54861911
Product type:	Medicine
Brand name:	-
Generic name:	Midazolam
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	-
Generic name:	Tolbutamide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	11-08-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-10-2014
Application type:	First submission
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	EUCTR2014-001794-14-NL
CCMO	NL50154.056.14