An open-label, mass balance study of 14C-JNJ-40411813 administered as a single oral dose in healthy male participants

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

Summary

ID

NL-OMON51781

Source
ToetsingOnline

Brief title
Mass balance study of 14C-JNJ-40411813 in healthy male participants

Condition

- Neuromuscular disorders

Synonym
epilepsy

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag

Source(s) of monetary or material Support: pharmaceutical industry

Intervention

Keyword: 14C, JNJ-40411813, mass balance, tolerability

Outcome measures

Primary outcome

Concentrations of JNJ-4041183, and metabolites in plasma.

Concentrations of total radioactivity in plasma and whole blood.

Amount of JNJ-40411813, and metabolites in urine.

Amount of total radioactivity in urine and feces (and samples of duodenal

fluid, if feasible).

As required, derived PK parameters of JNJ-40411813, and metabolites, and total

radioactivity.

Secondary outcome

Adverse events (AEs), significant changes in vital signs, ECG, safety

laboratory results, and C-SSRS

Study description

Background summary

The study will evaluate the study compound JNJ-40411813, which is being developed for the treatment of diseases such as epilepsy, anxiety and schizophrenia.

Study objective

The aim of this study is to investigate how quickly and to what extent JNJ-40411813 is absorbed, transported, and eliminated from the body. For this study, JNJ-40411813 is radioactively labelled with carbon-14 (14C). In this way JNJ-40411813 can be traced in blood, urine, and feces, and in duodenal fluid.

The liquid from the duodenum will be collected via a device called an EnteroTracker. The radioactivity is not harmful to the health.

We also investigate how safe JNJ-40411813 is and how well it is tolerated when it is used by healthy men.

Study design

the study takes about 10 weeks from the screening to the follow-up visit.

In total, the volunteer visits the research center a maximum of 5 times:
• once for the screening
• once for a stay in the research center of 16 days (15 nights). Day 1 is the day on which the research substance is administered. Departure from the research center is on Day 15 of the study.
• 2 visits of 24 hours (if necessary). If the radioactivity level in stool and urine has not yet reached predefined criteria on Day 15, the volunteer will return to the study center for 24-hour visits to collect urine and stool on Day 22 and, if necessary, also on Day 29. Departure is then on Day 23 and Day 30.
• a follow-up visit 8 to 12 days after the last stay in the research center.

the volunteer is given JNJ-40411813 as a 50 milliliter drink by mouth. After the administration of the study drug, the bottle will be rinsed three times with 50 ml of water, which the volunteer must also drink. After that, the volunteer has to drink another 40 ml of water, so that a total of 240 ml has been ingested.

The volunteer receives the study drug 30 minutes after the start of a standardized breakfast, which must be started right on time and eaten completely within 20 minutes.

Intervention

The volunteer receives 14C radiolabelled JNJ-40411813 once, 30 minutes after a standardized breakfast

Study burden and risks

Blood draw
Drawing blood may be painful or cause some bruising. The use of the indwelling cannula can sometimes lead to inflammation, swelling, hardening of the vein, blood clotting, and bleeding in the environment of the puncture site. In some individuals, a blood draw can sometimes cause pallor, nausea, sweating, low heart rate, or drop in blood pressure with dizziness or fainting.

In total, we will take about 487.7 milliliters (mL) of blood from you from

screening to follow-up. This amount does not cause any problems in adults. To compare: a blood donation involves 500 mL of blood being taken each time at once. If the investigator thinks it is necessary for the safety of a subject, extra samples might be taken for possible additional testing. If this happens, the total amount of blood drawn may be more than the amount indicated above.

Heart tracing
To make a heart tracing, electrodes (small, plastic patches) will be placed on your arms, chest and legs. Prolonged use of these electrodes can cause skin irritation (rash and itching).

Coronavirus test
Samples for the coronavirus test will be taken from the back of your nose and throat using swabs. Taking the samples only takes a few seconds, but can cause discomfort and can give an unpleasant feeling. Taking a sample from the back of your throat may cause you to gag. When the sample is taken from the back of your nose, you may experience a stinging sensation and your eyes may become watery.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Age: 18 (or the legal age of consent in the jurisdiction in which the study is taking place) to 55 years of age, inclusive.
2. Healthy on the basis of physical examination, medical history, vital signs, and 12-lead ECG performed at screening. If there are any abnormalities, they must be considered not clinically relevant, and this determination must be recorded in the participant's source documents and initialed by the investigator.
3. Healthy on the basis of clinical laboratory tests performed at screening. If the results of the serum chemistry panel, hematology, coagulation, or urinalysis are outside the normal reference ranges, the participant may be included only if the investigator judges the abnormalities or deviations from normal to be not clinically significant or to be appropriate and reasonable for the population under study. This determination must be recorded in the participant's source documents and initialed by the investigator.
4. Blood pressure (after the participant is supine for 5 minutes) between 90 mm and 140 mm Hg systolic, inclusive, and no higher than 90 mm Hg diastolic at screening. If blood pressure is out of range, up to 2 repeated assessments are permitted.
5. Must not have current COVID-19 infection, confirmed by SARS-CoV-2 polymerase chain reaction (PCR), on Day -1.
6. Weight : Body mass index between 18.0 and 30.0 kg/m2 (inclusive), and body weight not less than 50.0 kg.

Further criteria apply

Exclusion criteria

1. History of or current clinically significant medical illness including (but not limited to) cardiac arrhythmias or other cardiac disease, hematologic disease, coagulation disorders (including any abnormal bleeding or blood dyscrasias), lipid abnormalities, significant pulmonary disease, including bronchospastic respiratory* disease, diabetes mellitus, hepatic insufficiency, impaired hepatobiliary function (gall bladder removed, has a hepatobiliary shunt, etc), thyroid disease, neurologic or psychiatric disease**, infection, or any other illness that the investigator considers should exclude the participant or that could interfere with the interpretation of the study results.

*Participants with childhood asthma that resolved by the age of 12 years are eligible.
**Participants with a history of a suicidal attempt at any time in the past, or suicidal ideation within the past year, as measured by the Columbia-Suicide Severity Rating Scale (C-SSRS) baseline/screening version are excluded.
2. Participant has ALT or aspartate aminotransferase values >=1.5x the upper limit of normal (ULN) or total bilirubin >1.5 times the ULN at screening.
3. Creatinine clearance <=61 mL/min based on Chronic Kidney Disease Epidemiology Collaboration formula at screening.
4. History of malignancy within 5 years before screening (exceptions are squamous and basal cell carcinomas of the skin and carcinoma in situ of the cervix, or malignancy, which is considered cured with minimal risk of recurrence).
5. History of stomach or intestinal surgery or resection, including cholecystectomy, that would potentially alter absorption or excretion of orally administered drug (appendectomy and hernia repair will be allowed).

Further criteria apply

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):	03-11-2022
Enrollment:	7
Type:	Actual

Ethics review

Approved WMO

Date:	10-10-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-10-2022
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
Other	40411813EDI1013
EudraCT	EUCTR2022-002405-20-NL
CCMO	NL82169.056.22

Study results

Results posted: 24-07-2023

First publication
12-06-2023