A phase 1, open-label study to characterize the absorption, metabolism and excretion of 14C-JNJ-63623872 after a single dose in healthy male subjects

Published: 06-05-2015
Last updated: 19-04-2024

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

Summary

ID

NL-OMON42724

Source
ToetsingOnline

Brief title
JNJ-63623872 ADME study

Condition

- Viral infectious disorders

Synonym
Influenza A, RNA-virus

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: 14C, ADME, influenza A

Outcome measures

Primary outcome

The primary objective is to characterize the absorption and metabolic pathways

of JNJ-63623872, and the excretion of the compound and its metabolites, after

single oral dosing of 14C-JNJ-63623872 in healthy adult male subjects.

Secondary outcome

The secondary objective of this study is to determine safety and tolerability

for a single oral dose of 14C-JNJ-63623872 in healthy adult male subjects.

Study description

Background summary

JNJ-63623872 is a new investigational compound that may eventually be used for the treatment of influenza A. Influenza is an infectious disease, which infects the respiratory tract, caused by the influenza virus, a family of RNA viruses that infects also humans. JNJ-63623872 inhibits the reproduction of the influenza A virus in the human body by stopping the action of the virus polymerase, a protein that is responsible of the replication of the virus in the body cells.
JNJ-63623872 is not registered as a drug but has been given to humans before in several previous clinical studies.

Study objective

The purpose of the study is to investigate how quickly and to what extent JNJ-63623872 is absorbed, distributed, metabolized (broken down) and eliminated from the body (this is called pharmacokinetics). The compound to be

administered will be labeled with 14-Carbon (14C) and is thus radioactive (also called radiolabeled). This enables the investigator to trace the compound in blood, urine, feces, saliva and nasal mucus. The safety and tolerability of the compound will also be evaluated.

Study design

The actual study will consist of 1 period during which you will stay in the clinical research center in Zuidlaren for a minimum of 9 days (8 nights) and a maximum of 15 Days (14 nights).

On Day 1 the volunteer will receive the study compound in the form of three capsules after an overnight fast (at least 10 hours) with 240 milliliters of noncarbonated water, which the volunteer will have to drink entirely.

Intervention

The volunteer will receive a single 600 mg dose of JNJ-63623872 in the form of three capsules (200 mg per capsule).

Study burden and risks

JNJ-63623872 has been tested carefully in laboratory animals (mice, rats, dogs and monkeys) and it is considered generally safe and well tolerated in animals. The dose that we intend to give you is lower than the doses used in the animal studies.
JNJ-63623872 has been studied in single and multiple doses in healthy subjects, and in multiple doses in subjects infected artificially with influenza A.
JNJ-63623872 was generally safe and well tolerated. Approximately 228 subjects have been exposed to JNJ-63623872; 64 subjects have received a single dose of JNJ-63623872 (50 to 1600 mg) and 164 subjects have received multiple doses of JNJ-63623872 (up to 600 mg twice daily and up to 10 days of dosing). The adverse effects that occurred in subjects treated with JNJ-63623872 were reversible (disappeared on their own) and the majority of adverse effects were mild or moderate in severity.

Based on data collected in clinical trials conducted to date, the most common adverse effects are:

- Very common occurring in more than 1 in 10 subjects: Headache and diarrhea were seen at this frequency in healthy subjects and were considered by the investigator to be possibly related to study drug.
- In some subjects who were artificially infected with influenza A virus, brief mild to moderate elevations of liver enzymes and decreased blood phosphorus with no associated clinical symptoms were seen after study drug administration. These effects resolved without any treatment.

Registration of adverse effects: During the entire study all adverse effects you report will be documented.

Blood sampling, indwelling cannula: During this study less than 500 milliliters of blood will be drawn. An indwelling cannula will be used regularly to sample blood on Day 1. Remaining blood samples during pre-study screening, on Day -1, on Day 2 to Day 6, at discharge, and the post-study screening visit will be drawn by direct puncture of the vein. The blood samples are drawn to measure the amount of JNJ-63623872 and total radioactivity in your blood. Also certain blood samples are used for general checks of your health. At pre-study screening a check for hepatitis A, B and C and HIV (= AIDS-test) will be done on the blood sample.

Collection of urine and feces: Urine and feces will be collected from Day -1 onwards until Day 8 (after administration of JNJ-63623872) with a possible extension to Day 14. The urine and feces samples will be used to measure the amount of total radioactivity. Also certain urine samples are used for general checks of the volunteers health. At pre-study screening and on Day -1 a check for drugs of abuse and alcohol will be done on the urine sample.

Vital signs: Blood pressure, pulse rate, respiratory rate and body temperature will be measured regularly during the pre-study screening day, on Day 1, at discharge and during the post-study screening. This will occur in the supine and standing position.

Heart trace (ECG): ECGs will be made regularly: specifically during the pre-study screening, on Day 1, at discharge and during the post-study screening.

Physical examination: A physical examination will be done during pre-study screening, on Day -1, at discharge and during post-study screening. Your body weight and height will also be measured (height only at pre-study screening).

Saliva sampling: On Day 1, for a total amount of 6 times, saliva will be sampled. For this purpose the volunteer will be asked to spit in a collection tube until a pre-defined amount of saliva is collected. In the saliva samples the amount of JNJ-63623872 and total radioactivity will be determined.

Nasal Lavage: On Day -1 and on Day 1 the volunteer will undergo a nasal lavage (thus for a total of 2 times). The volunteers nose, both nostrils, will be rinsed with saline by using a syringe. After rinsing, the saline solution with nasal mucus included, will be collected and the amount of radioactivity will be determined. This procedure will be executed by the study staff.

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
18-60 years, inclusive
BMI: 18.0-30.0 kg/m2 inclusive

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

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):	18-05-2015
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	06-05-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-05-2015
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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	EUCTR2015-000719-42-NL
CCMO	NL53381.056.15