A phase 1, open-label study to characterize the absorption, metabolism, and excretion of 14C-JNJ-53718678 after a single oral dose in healthy adult male subjects

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

Summary

ID

NL-OMON43122

Source
ToetsingOnline

Brief title
JNJ-53718678 ADME study

Condition

- Viral infectious disorders

Synonym
RSV

Research involving
Human

Sponsors and support

Primary sponsor: Janssen Sciences Ireland UC
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: ADME, JNJ-53718678, RSV

Outcome measures

Primary outcome

- to determine the routes of excretion for JNJ-53718678 and its metabolites

after administration of a single oral dose of 14C-JNJ-53718678 in healthy adult

male subjects

- to explore the metabolic pathways of JNJ-53718678 after administration of a

single oral dose of 14C-JNJ-53718678 in healthy adult male subjects

- to determine the chemical structure of predominant metabolites

Secondary outcome

To determine safety and tolerability of a single oral dose of 14CJNJ- 53718678

in healthy adult male subjects.

Study description

Background summary

JNJ-53718678 is a new investigational compound that may eventually be used for the treatment of infections with RSV. RSV is a common virus that causes common colds. However especially in very young children an infection with RSV can result in lower respiratory tract infections and can cause very serious pneumonia. Also elderly persons and persons with underlying chronic diseases or a diminished immunity are at risk of developing serious illness. JNJ-53718678 binds to a specific protein on the surface of the RSV virus and thereby prevents the virus from entering cells in the body and multiplying inside these cells. JNJ 53718678 is in development and is not registered as a drug but has

been given to humans before in studies with single and multiple doses. The highest single dose of JNJ 53718678 given so far was 1000 mg, which is twice the amount (500 mg) the volunteer will receive in this study.

Study objective

The purpose of the study is to investigate how quickly and to what extent JNJ-53718678 is absorbed, distributed, metabolized (broken down) and eliminated from the body. JNJ-53718678 to be administered will be labeled with 14-Carbon (14C) and is thus radioactive (also called radiolabeled). In this way JNJ-53718678 can be traced in blood, urine, feces and duodenual fluid (the duodenum is the first part of the small intestine). It will also be investigated to what extent JNJ-53718678 is tolerated.

Study design

The study will consist of 1 period during which the volunteer will stay in the clinical research center in Groningen for minimally 7 days (6 nights) and maximally 11 days (10 nights).

During the study the volunteer will receive radiolabeled JNJ-53718678 after an overnight fast (at least 11 hours no eating and drinking) as an oral solution with 240 milliliters of tap water.

Intervention

The volunteer will receive a single dose of 500 mg radiolabeled JNJ-53718678 as an oral solution (50 milliliter).

Study burden and risks

Gastroscopy, placement of a nasoduodenal tube and duodenal fluid sampling are safe procedures and complications are rare. Usually these procedures are done without any problem. During the gastroscopy and placement of the nasoduodenal tube some people experience pain or gagging, have a feeling that they cannot breath, or are not able to swallow. Some people have a mildly sore throat for a day or so after gastroscopy. Nose bleeds and nausea are common after placement of a nasoduodenal tube. There is a slightly increased risk of developing a lung infection or pneumonia due to vomiting and aspiration during the procedure. The risk of this happening increases when the volunteer did not fast long enough. If, after removal of the nasoduodenal tube, he feels very nauseated or he has to vomit, the study doctor may treat this with certain medication. In rare cases the gastroscope or nasoduodenal tube may cause some damage to the gut. This may cause bleeding, infection and very rarely a small puncture (perforation). A small number of people can have a heart attack or a stroke during or soon after a gastroscopy but these tend to be older people who are

already in poor health. To minimize pain and discomfort, a gastroscope used in young children, in combination with local anesthesia is chosen as method for placement of the nose tube.

All potential drugs cause adverse effects; the extent to which this occurs differs. Up to February 2016, a total of 154 subjects have participated in studies with JNJ-53718678: 120 received at least one dose as single doses up to 1000 mg or multiple doses up to a total daily dose of 500 mg for up to 13 days. During these studies JNJ-53718678 was generally safe and well tolerated. Based upon the limited available clinical data, no known safety risks associated with JNJ 53718678 have been identified. The most frequently observed adverse effects in man are: headache, diarrhea, a bitter taste, nosebleed, tiredness, abdominal complaints and hot flushes. Other important adverse effects that were observed once are: inflammation of the gastrointestinal tract (gastroenteritis) and changes in the ECG. The volunteer should be aware that the aforementioned adverse effects and possibly other, still unknown adverse effects, may occur during the study. However, with the dose used in this study no serious adverse effects are expected.

In this study radiolabeled JNJ-53718678 will be used. The amount of radioactivity in this dose will be approximately 3.07 MBq (MBq = megaBecquerel, this is a unit to express the amount of radioactivity in the study compound). The average environmental background radiation burden in The Netherlands is approximately 2 mSv per year (mSv = milliSievert, this unit indicates the burden on the human body; thus the effect on the human body of the amount of radioactivity administered). The additional radiation burden in this study due to the administration of approximately 3.07 MBq radiolabeled JNJ-53718678 is calculated to be 0.07 mSv. This is approximately 3.5% of the average annual radiation burden.

Procedures: pain, minor bleeding, bruising, possible infection

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 - 55 yrs, inclusive
- BMI: 18.0 to 30.0 kg/m2, extremes included

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. Subject has received an experimental drug or experimental vaccine, or has used an experimental medical device within 1 month or within a period less than 10 times the drug*s half-life, whichever is longer, before scheduled study drug administration. Subject has donated blood or blood products or has had substantial loss of blood within 3 months before study drug administration or intention to donate blood or blood products during the study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	27-01-2017
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
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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	EUCTR2016-002664-14-NL
CCMO	NL59822.056.16

Study results

Date completed: 20-03-2017

Results posted: 05-09-2019

First publication
05-07-2019

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File
File