A phase 1, 4-period, crossover, open-label study in healthy volunteers to assess the effect of different types of food on a single-dose of JNJ-64417184 administered as tablets.

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Ethical review	Approved WMO
Status	Completed
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON48166

Source
ToetsingOnline

Brief title
Food effect study JNJ-64417184.

Condition

- Respiratory tract infections

Synonym
cold virus, respiratory syncytial virus (RS-virus)

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag International NV
Source(s) of monetary or material Support: Pharmaceutical/Biotechnological Industry.

Intervention

Keyword: Food effect, JNJ-64417184, Pharmacokinetic, RSvirus

Outcome measures

Primary outcome

• To evaluate the effect of 45 different types of food conditions on the single

dose PK of the JNJ184JNJ-64417184 tablet formulation administered orally, using

the PK after a high fat meal as a reference, in healthy subjects.

Secondary outcome

• To determine the PK parameters of JNJ-64417184 after a single dose.

• To assess the safety and tolerability of JNJ-64417184 after a single dose

when administered to healthy adult subjects.

Study description

Background summary

JNJ-64417184 is a new compound that may potentially be used for the treatment of infections with the respiratory syncytial virus (RS-virus). The RS-virus is a common virus that causes common colds. However, especially in very young children an infection with the RS-virus can result in lower respiratory tract infections and can cause very serious pneumonia. Also, elderly persons and persons with underlying chronic diseases or diminished immunity are at risk of developing serious illness. JNJ 64417184 is able to inhibit the RS-virus by inhibiting the viral protein production.

Study objective

The purpose of this study is to investigate how quickly and to what extent JNJ-64417184 is absorbed, distributed, metabolized and eliminated from the

body. The pharmacokinetics of JNJ-64417184 when it is administered in the morning following the intake of a high-fat breakfast will be compared to the pharmacokinetics of JNJ-64417184 when it is administered in the morning:
• following the intake of a standard breakfast
• the intake of a low-fat breakfast
• the intake of a balanced nutrition drink (Ensure* Original)
• under fasted conditions (no eating and drinking except water)

Further, it will be investigated how safe JNJ-64417184 is and how well it is tolerated.

JNJ 64417184 has been administered to humans before.

This study will be performed in approximately 20 healthy male or female volunteers.

Study design

The actual study will consist of 4 periods during each of which the volunteers will stay in the research center for 7 days (6 nights). In each treatment period, Day 1 is the day of administration of the study compound. In each treatment period, they are expected at the research center at 14:00 h in the afternoon prior to the day of administration of the study compound. In each treatment period, they will leave the research center on Day 6.

There will be at least 7 days between administration of the study compound in each period.

Intervention

The study consists of 4 treatment periods. In each treatment period, the volunteers will receive a single dose of 300 milligrams (mg) JNJ-6441784. The meal regimen prior to administration of JNJ-6441784 is different in each period. They will receive the high-fat breakfast on Day 1 in one of the 4 periods and they will undergo 3 of the other 4 meal regimens (standard breakfast, low-fat breakfast, nutrition drink or fasted conditions) on Day 1 in the other 3 periods. There will be 16 different meal regimen orders in this study and the volunteer will be assigned to one of these orders.

The different breakfast types must be started exactly on time in the morning and must be finished within 20 minutes. In each period, the entire breakfast must be consumed.

JNJ 64417184 will be given as an oral tablet (1 tablet of 300 mg) with 240 milliliters (mL) of water without chewing the tablet. In case the nutrition drink is the breakfast type, the tablet may be taken with 240 mL of water, but

it may also be taken without water.

The intake of water is not allowed from approximately 1 hour before until approximately 1 hour after intake of the study compound (except for the water used for intake of the study compound and for breakfast, if applicable). Following administration of JNJ 64417184, the volunteers will fast for a period of 4 hours, until scheduled lunch.

One of the investigators will inspect the hands and mouth after the study compound intake to see if you have swallowed the study compound.

Study burden and risks

Drawing blood and/or insertion of the indwelling cannula (tube in an arm vein) may cause lightheadedness, pain, bruising, and bleeding at the site of needle puncture, inflammation of the vein, and sometimes infection. On Day 1 of each period, blood will be sampled very frequently up to 24 hours after administration of the study compound to determine the course of the concentration of JNJ-64417184 in the blood over time.

In total, we will take maximally 500 mL of blood.

To make a heart tracing, electrodes (small, plastic patches) will be pasted at specific locations on the arms, chest and legs. Prolonged use of these electrodes can cause skin irritation (rash and itching).

Fasting at least 10 hours could cause dizziness, headache, stomach discomfort, or fainting.

The high-fat breakfast is a big breakfast consisting of 2 fried eggs, fried potatoes, and bacon among other things. the volunteers must consume the breakfast entirely. Particularly for small eaters, it can be difficult to consume the entire breakfast.

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

1. Male or female, 18 to 55 years of age, extremes included, at screening.
2. During the study (from the day of first study drug intake onwards) and for a minimum of 1 spermatogenesis cycle (defined as approximately 90 days) after the last study drug intake, a male subject must agree:
• To wear a condom when engaging in any activity that allows for passage of ejaculate to another person (male subject should also be advised of the benefit for a female partner to use a highly effective method of contraception as condom may break or leak);
• Not to donate sperm for the purpose of reproduction.
Contraceptive use should be consistent with local regulations regarding the use of contraceptive methods for subjects participating in clinical studies.
3. Female subjects must be of non-childbearing potential defined as:
• Postmenopausal
A postmenopausal state is defined as no menses for >12 months without an alternative medical explanation. A high follicle stimulating hormone (FSH) level (>40 IU/L or mIU/mL) in the postmenopausal range may be used to confirm a postmenopausal state in women not using hormonal contraception or hormone replacement therapy. In the absence of >12 months of amenorrhea, 2 FSH measurements have to be available, measured at least 3 months apart, OR
• Permanently sterile
Permanent sterilization methods include hysterectomy, bilateral salpingectomy, bilateral tubal occlusion/ligation procedures, and bilateral oophorectomy.
4. Must have a body mass index (BMI; weight [kg]/height2 [m2]) between 18.0 and 30.0 kg/m2, extremes included, and body weight not less than 50.0 kg at

screening.
5. Healthy on the basis of physical examination, medical and surgical history, and vital signs performed at screening. If there are abnormalities, the subject may be included only if the investigator judges the abnormalities to be not clinically significant or to be appropriate and reasonable for the population under study. This determination must be recorded in the subject's source documents and initialed by the investigator.
Further Criteria apply.

Exclusion criteria

1. Any evidence of heart block or bundle branch block at screening.
2. History of liver or renal dysfunction (calculated creatinine clearance/estimated glomerular filtration rate (eGFR) <60 mL/min at screening, calculated by the Modification of Diet in Renal Disease [MDRD] formula28), significant cardiac, vascular, pulmonary, gastrointestinal (such as significant diarrhea, gastric stasis, or constipation that in the investigator*s opinion could influence drug absorption or bioavailability), endocrine, neurologic, hematologic, rheumatologic, psychiatric, neoplastic, or metabolic disturbances.
3. Past history of cardiac arrhythmias (eg, extrasystoli, tachycardia at rest), history of risk factors for Torsade de Pointes syndrome (eg, hypokalemia, family history of long QT Syndrome).
4. Current HIV-type 1 (HIV-1) or HIV-2 infection (confirmed by antibodies) at screening.
5. History of hepatitis A, B, or C infection, or current hepatitis A infection (confirmed by hepatitis A antibody immunoglobulin M [IgM]), or HBV infection (confirmed by hepatitis B surface antigen), or HCV infection (confirmed by HCV antibody) at screening.
Further criteria apply.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	08-10-2019
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	17-09-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-10-2019
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	EUCTR2019-003469-17-NL
CCMO	NL71356.056.19

Study results

Date completed: 23-12-2019

Results posted: 09-06-2022

First publication
01-01-2021

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

Internal documents
File
File