A Phase 1, Open-Label Study in Healthy Adult Participants to Assess the Pharmacokinetics of JNJ-64281802 Administered as Different Multiple Dose Regimens

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

Summary

ID

NL-OMON51387

Source
ToetsingOnline

Brief title
JNJ-64281802 Multiple Dose Regimens

Condition

- Viral infectious disorders

Synonym
Dengue

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Healthy Adult, JNJ-64281802, Multiple Dose Regimens, Open-Label

Outcome measures

Primary outcome

To assess the PK of JNJ-64281802 in healthy participants when administered in

different multiple dose regimens and as different dose strengths.

Secondary outcome

To assess the safety and tolerability of JNJ-64281802 in healthy participants

when administered in different multiple dose regimens and as different dose

strengths.

Study description

Background summary

JNJ-64281802 is a new compound that may potentially be used for the treatment of dengue. Dengue (or dengue fever) is caused by the dengue virus, which is transmitted by mosquito bites. Dengue was almost eradicated in the 1970s, but has now spread to more than 125 countries. On average, each year about 500,000 dengue cases require hospitalization due to severe and life-threatening disease and up to 25,000 patients die due to dengue. JNJ 64281802 is currently being evaluated for the prevention and treatment of dengue infection, as it can inhibit the replication of the virus.

Study objective

In this study we will compare different dosing regimens with the study compound JNJ-64281802. We investigate how quickly and to what extent different doses JNJ-64281802 are absorbed, transported, and eliminated from the body when they are given at different time intervals. We also look how safe JNJ 64281802 is

and how well it is tolerated when it is used by healthy participants.

In treatment group 1, a device called TASSO-M20 will be used to draw blood in addition to regular blood draw. TASSO-M20 is a new device that should make it easier for patients to take samples of their own blood in the future. The blood concentrations of JNJ-64281802 measured in blood samples taken with the TASSO M20 device will be compared to the concentrations in the samples that are taken by direct puncture of a blood vessel. Subjects will use the device themselves, and they also have to take blood samples with this device themselves while they are at home.

We also look at the effect of genetic information on the body*s response to JNJ-64281802. This part of the study is mandatory.

JNJ-64281802 has been used by humans before. In addition, it has been extensively tested in the laboratory and on animals.

Study design

Group 1 and 3

Screening -> Day -28 to -2

Stay 1 -> Day -1 to 6
Stay 2 -> Day 9 to 11
Stay 3 -> Day 16 to 18
Stay 4 -> Day 23 to 29

Videocall (group 1 only) -> Day 30
Visit 1 -> Day 31
Visit 2 -> Day 38
Videocall (group 1 only) -> Day 40
Visit 3 -> Day 45
Visit 4 -> Day 51

Follow-up -> Day 59

Group 2 and 4

Screening -> Day -28 to -2

Stay 1 -> Day -1 to 7
Stay 2 -> Day 9 to 11
Stay 3 -> Day 12 to 14
Stay 4 -> Day 16 to 18
Stay 5 -> Day 19 to 21

Stay 6 -> Day 23 to 25
Stay 7 -> Day 26 to 29

Visit 1 -> Day 29
Visit 2 -> Day 30
Visit 3 -> Day 31
Visit 4 -> Day 34
Visit 5 -> Day 41
Visit 6 -> Day 48
Visit 7 -> Day 54

Follow-up -> Day 62

JNJ-64281802 with water

Intervention

Group 1 and 3:

Medication on Day 1, 2, 3, 10, 17 and 24

Group 2 and 4:

Medication on Day 1, 2, 3, 6, 10, 13, 17, 20, 24 and 27

Study burden and risks

Blood draw
Drawing blood may be painful or cause some bruising. The use of the indwelling cannula (a tube in a vein in the arm) can sometimes lead to inflammation, swelling, hardening of the vein, blood clotting, and bleeding in the environment (bruising) 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 not take more than 350 milliliters (mL) of blood 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 participant, 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 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 the 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 the throat may cause subjects to gag. When the sample is taken from the back of the nose, they may experience a stinging sensation and the eyes may become watery.

TASSO-M20 device (treatment group 1 only)
Minor bruising may occur around the sample collection site while using the TASSO-M20 device. Subjects will be seated while using the device. In total, we will take about 2.55 mL of blood with the TASSO-M20 device. In some individuals, a blood draw can sometimes cause pallor, nausea, sweating, low heart rate, or drop in blood pressure with dizziness or fainting. Drawing blood may be painful.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. 18 to 55 years of age, extremes included, at the time of screening.
2. Healthy on the basis of physical examination, medical history (at screening only), and vital signs performed at screening and Day -1. If there are abnormalities, the participant 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 participant's source documents.
3. Healthy on the basis of clinical laboratory tests performed at screening and Day -1. If the results of the serum chemistry panel, blood coagulation, hematology, or urinalysis are outside the normal reference ranges (except for those listed in the exclusion criteria), the participantmay 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.
4. Body weight not less than 50 kg and body mass index (BMI; weight kg/height^2 m^2) within the range 18.0 and 30.0 kg/m^2, extremes included, at screening and Day -1.
5. Man or woman

Exclusion criteria

1. History of or current clinically significant medical illness including (but not limited to) cardiac arrhythmias (eg, extrasystole, tachycardia at rest) or other cardiac disease, risk factors for Torsade de Pointes syndrome (eg, hypokalemia, family history of long QT Syndrome), hematologic disease, coagulation disorders (including any abnormal bleeding or blood dyscrasias), lipid abnormalities, significant pulmonary disease, including bronchospastic respiratory disease, diabetes mellitus, hepatic or renal insufficiency (creatinine clearance below 60 mL/min at screening, calculated by the Modification of Diet in Renal Disease [MDRD] formula, vascular, gastrointestinal (such as significant diarrhea, gastric stasis, or constipation that in the investigator's opinion could influence drug absorption or bioavailability), rheumatologic, neoplastic, endocrine, thyroid disease, neurologic or psychiatric disease, infection, metabolic disturbances, or any other illness that the investigator considers should exclude the participant or that could interfere with the

interpretation of the study results.
2. Participants with one or more of the following laboratory abnormalities at screening, as defined by the World Health Organization (WHO) Toxicity Grading Scale and in accordance with the normal ranges of the clinical laboratory if no gradings are available:
- Serum creatinine elevation Grade 1 or greater (>=1.1×upper limit of normal [ULN])
- Hemoglobin lowering Grade 1 or greater (<=10.5 g/dL)
- Platelets count lowering Grade 1 or greater (<=99,000/mm^3)
- Absolute neutrophil count lowering Grade 1 or greater (<=1,500/mm^3)
- Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) elevation Grade 1 or greater (>=1.25 ×ULN)
- Total bilirubin Grade 1 or greater (>=1.1 ×ULN)
- Any other laboratory toxicity Grade 2 or greater (for elevations of triglycerides, low-density lipoprotein (LDL) cholesterol, and/or total cholesterol: Grade 3 or greater).
3. Any history of clinically significant skin disease such as, but not limited to, dermatitis, eczema, drug rash, psoriasis, food allergy, and urticaria.
4. Known allergies, hypersensitivity, or intolerance to JNJ-64281802 or its excipients.
5. Has been dosed with JNJ-64281802 in past 3 months.

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):	17-02-2022
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	09-02-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-02-2022
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
EudraCT	EUCTR2021-005574-25-NL
CCMO	NL80079.056.22

Study results

Results posted: 08-12-2023

First publication
23-11-2023