A 3-Part, Randomized, Placebo-Controlled, Double-blind, Single Ascending Dose Study to Investigate Safety and Tolerability, Pharmacokinetics and Pharmacodynamics of JNJ-55363932 in Healthy Participants.

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Primary- To investigate the safety and tolerability of JNJ-55363932 after single oral dose administration(ascending dose levels) in healthy participants- To characterize the PK of JNJ-55363932 in plasma, cerebrospinal fluid (CSF) and urine...

Ethical review	Approved WMO
Status	Completed
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON51472

Source
ToetsingOnline

Brief title
55363932EDI1001

Condition

- Psychiatric disorders NEC

Synonym
psychiatric disorders

Research involving

Human

Sponsors and support

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

Intervention

Keyword: JNJ-55363932, PD, PK

Outcome measures

Primary outcome

- Clinical labs (chemistry, hematology, urinalysis, coagulation [only Part 2])

- Adverse events (AE)

- (Holter) ECG and telemetry

Plasma, CSF (only Part 2), and urine concentrations (only Parts 1 and 3) of

JNJ-55363932 and when feasible, potential metabolites and plasma protein

binding

Secondary outcome

As assessed by NeuroCart parameters and resting state

phamacoelectroencephalogram

(phEEG)

Study description

Background summary

The purpose of this study is to investigate the safety and tolerability of JNJ-55363932 after single oral dose administration (ascending dose levels) in healthy participants and to characterize the pharmacokinetics (PK) of

JNJ-55363932 in plasma, cerebrospinal fluid (CSF) and urine after single oral dose administration in healthy participants.

Study objective

Primary
- To investigate the safety and tolerability of JNJ-55363932 after single oral dose administration
(ascending dose levels) in healthy participants
- To characterize the PK of JNJ-55363932 in plasma, cerebrospinal fluid (CSF) and urine after
single oral dose administration in healthy participants

Study design

First-in-human, 3-part, randomized, placebo-controlled, double-blind, single ascending dose (SAD) study in healthy participants.

Intervention

JNJ-55363932

Study burden and risks

There are no reproductive or developmental toxicology data yet available for JNJ-55363932 and
no studies have examined the effects of JNJ-55363932 in pregnancy. Therefore, only young
healthy male participants will be administered study intervention. This will also reduce variability
in PK, and possibly PD, results. In Part 2 only, healthy middle-aged and elderly WONCBP and
male participants aged 40-75 years may be included. There is evidence showing that middle and
elderly individuals have lower rates of post-lumbar puncture headache compared to younger
individuals.

JNJ-55363932 was evaluated in toxicity studies in preclinical animal species. Increases in blood pressure
and changes in HR were observed. To mitigate this risk in this study, blood pressure and HR, will
be monitored frequently for 96 hours. Thresholds will be set to alert the site staff of significant
increases (or decreases). These data will be reviewed at the Data Visualization (DV) meetings to

evaluate if protocol stopping criteria have been met.

This study will be performed in healthy participants who will receive no benefit from participation in the study, except for financial compensation for the time and inconveniences that may arise from participation in the study. However, the results of the investigation of JNJ-55363932 may help future patients.

Taking into account the measures taken to minimize risk to participants of this study, the potential risks identified in association with JNJ-55363932 are justified by the anticipated benefits that may be afforded to participants with psychiatric disorders.

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 based on physical examination, medical history, vital signs, and 12-lead electrocardiogram (ECG) performed at screening and admission to the clinical unit
- In Part 2, a woman must not be of childbearing potential
- Participant has a body mass index (BMI) between 18 and 30 kilogram per meter square (kg/m^2) inclusive

Exclusion criteria

- History of or current significant medical illness including (but not limited to) cardiac arrhythmias or other cardiac disease, hypertension, hematological disease, lipid abnormalities, bronchospastic respiratory disease, diabetes mellitus, renal or hepatic insufficiency, thyroid disease, Parkinson*s disease, infection, or any other illness that the investigator considers should exclude the participant
- Has had a clinically significant acute illness within 14 days prior to study intervention administration
- Has had major surgery, (for example, requiring general anesthesia) within 8 weeks before screening, or will not have fully recovered from surgery, or has surgery planned during the time the participant is expected to participate in the study or within 4 weeks after the last dose of study intervention administration
- History of malignancy within 5 years before screening (exceptions are squamous and basal cell carcinomas of the skin, or malignancy that in the opinion of the investigator, with written concurrence with the safety responsible physician, is considered cured with minimal risk of recurrence)
- Has acute symptoms of coronavirus disease 19 (COVID-19) infection or sequelae at Day -1 or has had a positive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) test after admittance to the clinical unit or at any of the repeat tests
- For part 2 only: Has a significant coagulation abnormality (for example, hemophilia, platelet counts less than the lower limit of normal or clinically significant elevation in prothrombin time [PT] or activated partial thromboplastin time [aPTT] at screening) or has a medical condition requiring treatment with an anticoagulant (for example, warfarin) or with two or more antiplatelet agents. Platelet counts between 125,000 and 150,000/microliter are permissible if the investigator confirms there is no evidence of current bleeding diathesis or coagulopathy, and having a contraindication for spinal puncture
- Has a diagnosis or suspicions of any sleep disorder in the last 6 months or

current complaints of sleep disturbance, irregular sleep schedule or shift work; habitual daytime naps; travel across 3 different time zones in the last 2 weeks or daytime symptoms attributable to unsatisfactory sleep
- Has undergone major lifestyle changes in the previous 6 months: significant weight loss greater than (>) 5 kg or started a specific diet which could potentially result in weight loss

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-03-2022
Enrollment:	109
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	N.a.
Generic name:	JNJ-55363932

Ethics review

Approved WMO

Date:	16-12-2021
Application type:	First submission

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-01-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-04-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-05-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-05-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-06-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-06-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-07-2022
Application type:	Amendment
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	EUCTR2021-003959-41-NL
CCMO	NL79810.056.21