A First-in-Human Study to Evaluate Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single Escalating Oral Doses of JNJ 28431754 in Healthy Male Subjects

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON30637

Source
ToetsingOnline

Brief title
N/A

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes Mellittus type II

Research involving
Human

Sponsors and support

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

Intervention

Keyword: dose escalation, pharmacokinetics, safety, tolerability

Outcome measures

Primary outcome

safety and tolerability, pharmacokinetic and pharmacodynamic blood and urine

tests, adverse events, safety laboratory parameters, vital signs, heart rate,

ECG, alcohol breath test and continuously hearth rhythm (telemetry) and Fecal

Occult Blood Test (FOBT).

Secondary outcome

NA

Study description

Background summary

JNJ-28431754 is an investigational drug being developed for the treatment of type 2 diabetes mellitus.

Study objective

Part 1 of the study has two objectives. Firstly, we will study the safety and tolerability of the drug after the administration of single ascending oral doses of the drug. Secondly we will study the pharmacokinetics and pharmacodynamics. This means that we investigate the effect of the study drug and the speed at which the drug is absorbed, distributed, broken down and eliminated in the body.
In Part 2 of the study we will investigate whether food, when given together with JNJ-28431754, will affect the safety, tolerability, pharmacodynamics and pharmacokinetics of JNJ-28431754.

Study design

This is a single center study in healthy male subjects who will receive a single ascending dose of JNJ-28431754 or placebo. The study consist of Part 1 and Part 2.
Part 1:
Six or more groups of each eight healthy male volunteers, will participate in this part of the study. The study will include a medical screening, one admission period of 7 days and finally a follow-up visit 10 to 14 days after dosing. The current Amendment describes the investigation of the effect of twice daily dosing. For that reason an additional group will be added.
The subjects will be admitted to the unit on Day -2.
On Day -1, the baseline assessments will be done.
In the morning of Day 1 the subjects will receive a single oral dose of study drug JNJ-28431754 or placebo in a fasted state.
The doses of JNJ-28431754 will be escalated in a stepwise fashion if the safety, tolerability and pharmacokinetic profile (uo to 48 hours post dosing) is found acceptable after assessments of preceding dose level(s).
Part 2:
One group of 8 healthy male volunteers will participate in this part of the study.
Part 2 consists of two periods. The study will include a medical screening, two admission periods of 6 days and finally a follow-up visit 10 to 14 days after the last dosing.
The subjects will be admitted to the unit on Day -1.
In the morning of *Day 1* of each period one single oral dose of JNJ-28431754 or placebo with or without a standardized high fat meal will be administered. This will be determined by chance. The two periods will be separated by about 14-days wash out period.

Intervention

Each subject is only allowed to participate after randomisation to one of the cohorts.
During part 1, a one single dose of JNJ-28431754 or placebo is administered. The extra group will be dosed, twice daily.
Part 2, consist of 2 periods, separated by about 14-days wash out period.
On day 1 of each period the subject receives a one single dose of JNJ-28431754 or placebo, with or without a standardized high fat meal.

Study burden and risks

The associated risks to this study are the occurence of possibility side effects of the use of JNJ-28431754. The burden of the subjects are the confinement period in the unit, venapuncture, the insertion of the canula and connection of the telemetry equipment. All subjects will be carefully monitored

regarding possible adverse events by experienced study personnel and physicians.

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, non-smoking males, aged 18-55 years

Exclusion criteria

Positive FOBT at screening or admission (Day -1)
Positive H. pylori IgG Ab test result from the Chemiluminescence Immunoassay or urea

breath test, at screening
History of disorders that are potential causes of occult GI bleeding
History of, or currently active, significant illness or medical disorders
Male subjects who are not sterile and are unwilling to use condoms for the duration of the study (and until 90 days after the last dose of study medication).
Tested positive for serology: hepatitis B surface antigen (HBsAg), hepatitis C antibodies (anti-HCV) or human immunodeficiency virus (HIV) antibodies.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2006
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO Date:	06-11-2006
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	09-11-2006
Application type:	First submission

Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	11-12-2006
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	22-12-2006
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	09-03-2007
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	13-03-2007
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2006-005516-27-NL
Other	N/A
CCMO	NL15048.040.06