A Randomized, Double-Blind, Placebo-Controlled Study in Healthy Male Subjects to Evaluate the Safety, Tolerability, and Pharmacokinetics of Single Ascending Oral Doses of JNJ-26070109

Published: 01-06-2006
Last updated: 20-05-2024

JNJ-2607019 is an investigational drug being developed for gastroesophageal reflux disease (GERD) to reduce the complaints of abdominal pain and heartburn in people with this disease. JNJ-26070109 inhibits the gastrin receptor in the stomach. The...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON30044

Source
ToetsingOnline

Brief title
N/A

Condition

- Gastrointestinal conditions NEC

Synonym
abdominal pain and heartburn

Research involving

Human

Sponsors and support

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

Intervention

Keyword: dose escalation, pharmacokinetic, safety, tolerability

Outcome measures

Primary outcome

Safety and tolerability, pharmocokinetic and pharmacodynamic blood and urine tests, adverse events, safety laboratory parameters, vital signs, heart rate, ECG, alcohol breath test and continuously hearth rhythm (telemetry) . For cohort 8 also intra-gastric pH measurements will be assessed for a period of 48 hours, starting on Day -1 and finished 24 hours after dosing.

Secondary outcome

Not applicable

Study description

Background summary

The study has three objectives. Firstly, we will study the safety and tolerability of JNJ-26070109 after single increasing dose administration of the drug. Secondly, we will study the speed at which the drug is absorbed in the body, as well as the effects of the drug and the extent to which it is metabolised. Thirdly, we will investigate the maximum tolerated concentration in the body.

Study objective

JNJ-2607019 is an investigational drug being developed for gastroesophageal reflux disease (GERD) to reduce the complaints of abdominal pain and heartburn

in people with this disease. JNJ-26070109 inhibits the gastrin receptor in the stomach. The gastrin receptors are small particles in the stomach. When the gastrin receptor is triggered the stomach will produce acid. In people with GERD the acid in the stomach is the cause for the abdominal pain and heartburn. By blocking the gastrin receptor the acid production will decrease and the complaints of pain and heartburn will diminish.

Study design

This is a single center study in healthy male subjects, and consists of 2 parts. Part One is a double-blind, randomized, placebo-controlled single ascending dose design. Subjects will participate in one of seven (7) cohorts (n = 10) and will receive either JNJ 26070109 oral suspension (n = 7) or placebo (n = 3) after an overnight fast. Dose escalation will continue until maximum tolerated dose (MTD) is reached per the dose limiting toxicity (DLT) described in Section (4.7.6). The doses of JNJ 26070109 will be escalated in a stepwise fashion if the safety, tolerability and pharmacokinetic profile (up to 24 hours post dosing) is found acceptable after assessment of the preceding dose level(s). Each dose escalation will not exceed 4 fold of the previous dose and the dose will not exceed 1000 mg.
Part Two of the study is an open-label, single dose design to evaluate the effect of JNJ-26070109 on intra-gastric pH. Subjects that participated in Part One are not eligible to participate in Part Two. Twelve (12) healthy male subjects will be enrolled. Subjects will have 24-hour intra-gastric pH measurements on two consecutive days: at baseline for 24 hours prior to dosing (first 24 hours; Day *1) and following dosing with JNJ 26070109 oral suspension (second 24 hours; Day 1). The dose to be administered in Part Two will be the MTD, or the highest dose administered in Part One, if the MTD is not reached. This dose may be administered as a single dose or in divided doses on Day 1 based on Part One results.
The total duration per subject is 38 days at a maximum. The study will include a medical examination, one admission period of 5 days, one visit and finally a follow-up. For the last group of 12 healthy male volunteers the study will include a medical examination, one admission period of 6 days, one visit and finally a follow-up. The following assessments will be taken; physical exam, blood-and urine sample collections, alcohol breath test, blood sample for DNA-assessment, vital signs, ECG*s and continuously hearth rhythm (telemetry). For group 8, also intra gastric pH monitoring will be assessed for a period of 48 hours.

Intervention

Every subject is only allowed to participate after randomisation to one of the cohorts.

Cohort 1: single oral dose of 5 mg of JNJ-26070109 suspension or placebo

Cohort 2: single oral dose of 15 mg of JNJ-26070109 suspension or placebo
Cohort 3: single oral dose of 50mg of JNJ-26070109 suspension or placebo
Cohort 4: single oral dose of 150mg of JNJ-26070109 suspension or placebo
Cohort 5: single oral dose of 400 mg of JNJ-26070109 suspension or placebo
Cohort 6: single oral dose of 700 mg of JNJ-26070109 suspension or placebo
Cohort 7: single oral dose of 1000 mg of JNJ-26070109 suspension or placebo

Cohort 8: Dose administration ofxxxx mg of JNJ-26070109 suspension or placebo. The dose to be administered will be the MTD, or the highest dose administered in the previous cohorts, if the MTD is not reached. This dose may be administered as a single dose or in divided doses on Day 1 based on Part One results.

Study burden and risks

The associated risks to this study are the occurrence of possibility side effects of the use of JNj-26070109. The burden of the subjects are the confinement period in the unit, venipuncture, the insertion of the cannula and connection of the telemetry equipment. For cohort 8 also the insertion of the gastric tube. All subjects will be carefully monitored regarding possible adverse events by experienced study personnel and physicians.

Contacts

Public
Janssen-Cilag

Dr. Paul Janssenweg 150
5026 RH Tilburg
Nederland
Scientific
Janssen-Cilag

Dr. Paul Janssenweg 150
5026 RH Tilburg
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy males without evidence of gastro-intestinal disorders

Exclusion criteria

Subjects with evidence of clinically significant reproductive, gastrointestinal, renal, hematologic, pulmonary, neurologic, respiratory, endocrine/metabolic, or cardiovascular system abnormalities, psychiatric disorders, oncologic conditions or acute or chronic infection.
Subjects with a history of any hepatic disorder or history of hepatitis.
Subjects with known elevations of LFTs, alkaline phosphatase, gamma-GT, or bilirubin in the past.
Negative Helicobacter pylori serum IgG antibody

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:	Recruitment stopped
Start date (anticipated):	08-06-2006
Enrollment:	82
Type:	Actual

Ethics review

Approved WMO Date:	01-06-2006
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	08-06-2006
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	01-12-2006
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	EUCTR2006-001738-42-NL
CCMO	NL12645.040.06