A phase 1, randomized, double-blind, placebo-controlled, ascending dose study evaluating the safety, tolerability and pharmacokinetics of JTK-652 administered for two weeks in healthy male subjects

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Primary objectives : to investigate the safety and tolerability of multiple oral doses of JTK-652 administered for 14 days to healthy male subjectsSecondary objectives : tot determine the pharmacokinetics of multiple oral doses of JTK-652…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON31189

Source
ToetsingOnline

Brief title
JTK-652 multiple ascending dose study

Condition

- Hepatic and hepatobiliary disorders
- Viral infectious disorders

Synonym
Hepatitis

Research involving
Human

Sponsors and support

Primary sponsor: Japan Tobacco, Inc.
Source(s) of monetary or material Support: sponsor van dit onderzoek

Intervention

Keyword: Hepatitis C, JTK-652, Multi ascending dose

Outcome measures

Primary outcome

Safety : AE's, clinical laboratory parameters, vital signs, ECG and physical

examination

Pharmacokinetics : plasma JTK-652 concentrations, pharmacokinetics parameters

Secondary outcome

Nvt

Study description

Background summary

Infection with hepatitis-C virus (HCV)is now the most frequent cause of chronic hepatitis, cirrhosis and hepatocellular carcinoma in most developed nations. HCV is a blood borne pathogen that is transmitted predominantly by percutaneous exposure. JTK-652 could be useful for treatment. JTK-652 shows an inhibitory effect on liver cells that are hepatitis-C infected. Other than the current protease inhibitors in development, JTK-652 is likely to have its action in the early phase of the infection process.

Study objective

Primary objectives : to investigate the safety and tolerability of multiple oral doses of JTK-652 administered for 14 days to healthy male subjects
Secondary objectives : tot determine the pharmacokinetics of multiple oral

doses of JTK-652 administered for 14 days to healthy male subjects

Study design

Randomized, double-blind, placebo-controlled, ascending dose study in 18 healthy male subjects in two dose cohorts with nine subjects each. In each cohort nine subjects (6 active, 3 placebo) will be randomized to receive JTK-652 or placebo every 8 hours for 13 days with a final morning dose on Day 14.

Intervention

Cohort 1 : three times daily (t.i.d.) an oral dose of 400 mg JTK-652 or placebo on Days 1-13 with a final dose on Day 14.
Cohort 2 : t.i.d. an oral dose of 800 mg JTK-652 or placebo on Days 1-13 with a final morning dose on Day 14

Study burden and risks

Procedures; insertion of the indwelling canula/venapuncture : some pain, bruise, light bleeding.

JTK-652:
adverse effets in animal studies: vomiting, abnormal feaces (whitish and soft stool, or diarrhoea), slight increased liver enzyme and fat change in specific liver cells, hypertrophy sinusoidal cells in liver (not associated with changes in bleeding), mild increase in thyroid weight and increase in size of typical cells in the thyroid. At very high doses sensivity for sun light was found.

Contacts

Public
Japan Tobacco, Inc.

JT BLdg. 2-1, Toranomon 2-chrome
Minato-ky, Tokyo, 105-8422
Japan
Scientific
Japan Tobacco, Inc.

JT BLdg. 2-1, Toranomon 2-chrome
Minato-ky, Tokyo, 105-8422
Japan

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Man
Age : 18-55 yr
BMI : 19-28 kg/m2, inclusive

Exclusion criteria

Current abuse of alcohol or/and drugs
Clinical significant indications in man's medical history

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):	15-10-2007
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	11-09-2007
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-09-2007
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	EUCTR2007-004230-17-NL
CCMO	NL19571.056.07