Phase I, double blind, randomized, placebo-controlled trial in healthy subjects to examine the safety, tolerability and pharmacokinetics of increasing oral doses of TMC435350 after single and repeated dosing, followed by an open label repeated dosing session in 6 HCV-genotype 1 infected patients (non placebo-controlled).

Published: 08-01-2007
Last updated: 14-05-2024

See comments at the Dutch section

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

Summary

ID

NL-OMON30518

Source
ToetsingOnline

Brief title
TMC435350, SRD and MRD study (FIH)

Condition

- Viral infectious disorders

Synonym
hepatitis-C infections

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: Tibotec Pharmaceuticals Ltd;Little Island;Co Cork;Ierland

Intervention

Keyword: pharmacokinetics, safety, tolerability

Outcome measures

Primary outcome

See comments at the Dutch section

Secondary outcome

See comments at the Dutch section

Study description

Background summary

See comments at the Dutch section

Study objective

See comments at the Dutch section

Study design

See comments at the Dutch section

Intervention

See comments at the Dutch section

Study burden and risks

See comments at the Dutch section

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 subjects aged between 18 and 55 years.
Non-smokers for at least 3 months prior to selection
Normal weight as defined by a BMI of 18.0 to 30.0 kg/m2. Normal 12-lead ECG
Patients:
Subjects aged between 18 and 70 years, extremes included
Able to comply with protocol requirements and having good accessible veins.

Subjects with chronic Genotype 1 HCV infection, non-responders to previous treatment regimens (being interferon/ ribavirin or pegylated interferon/ribavirin)

Exclusion criteria

Past history of heart arrhythmias or having baseline prolongation of QTc interval > 450 ms, history of risk factors for Torsade de Pointes syndrome or evidence of cardiomyopathy as evidenced by a grade 1 or higher decrease in EF/SF.
Female, except if postmenopausal since more than 2 years, or post-hysterectomy, or post tubal ligation.
Confirmed Hepatitis A, B, or C infection, or cancer or HIV/AIDS.
Participation in an investigational drug trial within 30 days prior to the first intake of trial medication.
Donation of blood or plasma within 60 days preceding the first intake of trial medication.
Patients:
Subjects co-infected with HIV-1, HIV-2 or any hepatitis infection other than HCV.
Male subjects with female partners of childbearing potential not agreeing to use a reliable birth control method for 90 days after the last dosing in the study.
Subjects on non stable methadone use, on non stable anti-hypertensive treatment or on non stable antidepressant treatment.

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):	03-02-2007
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Norvir
Generic name:	Ritanovir
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	08-01-2007
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-01-2007
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-01-2007
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-04-2007
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-05-2007
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-05-2007
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	EUCTR2006-006455-12-NL
CCMO	NL15888.056.06