A two-period microdosing study to determine the single-dose pharmacokinetics of ITMN-8187 after intravenous and oral administration in healthy subjects.

Published: 15-02-2010
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Primary:- to determine the pharmacokinetics (PK) of parent drug and total radioactivity after administration of the studydrugSecondary:- to determine the absolute bioavailability of ITMN-8187 after oral administration- to investigate the safety and...

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

Summary

ID

NL-OMON34901

Source
ToetsingOnline

Brief title
[14C]-ITMN-8187 microdose study

Condition

- Viral infectious disorders

Synonym
Hepatitis C, virus

Research involving
Human

Sponsors and support

Primary sponsor: Intermune
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: Hepatitis C, ITMN-8187

Outcome measures

Primary outcome

Pharmacokinetics

Safety

Secondary outcome

n.a.

Study description

Background summary

The drug to be given is a new, investigational compound that may eventually be used for the treatment of hepatitis C. The studydrug, a protease inhibitor, is expected to block an enzyme involved in the replication of the virus. As such the studydrug may be beneficial for hepatitis C patients.

Study objective

Primary:
- to determine the pharmacokinetics (PK) of parent drug and total radioactivity after administration of the studydrug

Secondary:
- to determine the absolute bioavailability of ITMN-8187 after oral administration
- to investigate the safety and tolerability
- to obtain plasma and urine samples which may be used in further PK and metabolism profiling evaluation of the studydrug

Study design

Design:
An open-label, non-randomised study.

Procedures and assessments
Screening:
Medical history, demographic data (including body weight and height), clinical laboratory, alcohol and drug screen, HBsAg, anti HCV, anti-HIV 1/2, vital signs, 12-lead electrocardiogram (ECG), physical examination, adverse events from the signing of the Informed Consent Form, previous and concomitant medication.

Admission:
Drug and alcohol screen, AEs and concomitant medication.

Follow-up:
Clinical laboratory, vital signs, ECG, physical examination, AEs and concomitant medication.

Observation period:
- up to 72 h after drug administration

Blood sampling:
oral administration
- for PK of the studydrug and for total radioactivity in plasma: up to 72 h post-dose

iv infusion
- for PK of the studydrug and for total radioactivity in plasma: up to 72 h after the end of the infusion

Urine sampling:
- for PK of the studydrug and for total radioactivity in urine: up to 48-72 h post-dose

Safety assessments:
AEs: recorded from the time the Informed Consent Form is signed until completion of the final visit; concomitant medication; clinical laboratory: screening, each period at pre-dose and at 72 h post-dose and at the follow-up visit; vital signs: each period at pre-dose and up to 72 h post-dose; 12 lead ECG: each period at pre-dose and up to 72 h post-dose and at the follow-up visit; physical examination: at screening and at the follow-up visit.

Bioanalysis:
Analysis of plasma and urine samples for the studydrug and total radioactivity by the Sponsor using a validated accelerator mass spectrometry (AMS) method.

Intervention

Active substance: ITMN-8187 (radiolabeled)

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection.

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 male volunteers
- age between 18 and 65 years

- BMI is between 18.0 and 32.0 kg/m2
- non smoker or light or moderate smoker, i.e. * 5 cigarettes a day
- at screening the state of health must satisfy the entry requirements

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/AIDS. In case of participation in another drug study within 60 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-02-2010
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

Date:	15-02-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	18-02-2010
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	EUCTR2010-018400-93-NL
CCMO	NL31501.056.10