A Multiple Dose Study to Evaluate Safety, Pharmacokinetics, and Pharmacodynamics of MK-8408 in Subjects with Hepatitis C Infection

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-To identify a safe dose of MK-8408 in HCV infected patients that mediates a 3Log10 reduction-To evaluate safety and tolerability of MK-8408 administered for 5 consecutive days-To evaluate the plasma pharmacokinetic profile of multiple oral doses of...

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

Summary

ID

NL-OMON41065

Source
ToetsingOnline

Brief title
MK8408-003

Condition

- Viral infectious disorders

Synonym
Hepatitis C

Research involving
Human

Sponsors and support

Primary sponsor: Merck Sharp & Dohme (MSD)

Source(s) of monetary or material Support: Merck

Intervention

Keyword: Hepatitis C, Patients, Pharmacodynamics, Safety

Outcome measures

Primary outcome

Viral load

safety

tolerability

Secondary outcome

plasma pharmacokinetic (PK) profile

Study description

Background summary

MK-8408 is a HCV NS5a inhibitor for the potential treatment of HCV infection. The purpose of this trial is to investigate safety, pharmacokinetics and pharmacodynamics in HCV infected patients.

Study objective

-To identify a safe dose of MK-8408 in HCV infected patients that mediates a 3Log10 reduction
-To evaluate safety and tolerability of MK-8408 administered for 5 consecutive days
-To evaluate the plasma pharmacokinetic profile of multiple oral doses of MK-8408 in HCV infected patients

Study design

This is a three-part, multiple panel, multi-site, open label trial of MK-8408 in subjects with Hepatitis C Virus (HCV) infection of genotype GT3 (Part I), GT1a (Part II) and GT2b (Part III), to be conducted in conformance with Good Clinical Practices.

Intervention

The study will start with a screening visit. During the screening visit standard medical assessments including safety laboratory tests (blood draw, urine collection), an alcohol breath test, urine drug screen, a physical examination, ECG and a vital signs measurement will be performed.

During the study the subjects will stay in the unit on certain days or return to the unit to receive study medication on 5 subsequent days. After these 5 days of dosing, there are some visits to the site for blood collection and a follow up visit. During all the visits (up to Day 61) and during the stays in the unit, subjects will be asked on a regular base for possible side effects, blood will be drawn for safety, PK and PD measurements and other standard safety assessment (VS, ECG, lab safety tests,*) can be performed during these days.

Study burden and risks

Single doses of MK-8408 have been generally safe and well-tolerated by the subjects in the first study with MK-8408. No serious adverse experiences have been reported and no subject has been discontinued by the Investigator. Adverse experiences have been mild to
moderate in intensity and transient in duration. Twelve (12) subjects have reported adverse experiences. Since the trial is still blinded, it is not known if these adverse events were experienced by subjects receiving active drug or placebo. The reported adverse experiences are headache (19), photophobia (1), nausea (1), sore throat (1), and ecchymosis at the site of a blood draw (1). There have been no consistent treatment-related changes in laboratory, vital signs, or ECG safety parameters.

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

1. Male or Female (of non-child bearing potential) subjects with verified HCV infection with GT1a, GT2b or GT3 between the ages of 18 and 65 years (inclusive)
2. have a Body Mass Index (BMI) >=18 to <=37 kg/m2
3. Be judged to be in good health, except for HCV infection

Exclusion criteria

1. Subject is mentally or legally institutionalized / incapacitated, has significant emotional problems at the time of pretrial (screening) visit or expected during the conduct of the trial or has a history of clinically significant psychiatric disorder of the last 5 years.
2. Subject has a history of clinically significant endocrine, gastrointestinal, cardiovascular, hematological, hepatic, immunological, renal, respiratory, genitourinary or major neurological (including stroke and chronic seizures) abnormalities or diseases.
3.Subject has a history of cancer.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-08-2014
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	MK-8408
Generic name:	Nap

Ethics review

Approved WMO Date:	01-07-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-08-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-03-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-03-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-11-2015

Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-11-2015
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	EUCTR2013-005094-41-NL
ClinicalTrials.gov	NCT02076100
CCMO	NL49675.056.14