A Phase I, open-label, randomized, 2-way crossover trial in 40 healthy subjects to investigate the potential pharmacokinetic interactions between telaprevir and darunavir/ritonavir and between telaprevir and fosamprenavir/ritonavir at steady-state

Published: 23-05-2008
Last updated: 11-05-2024

The primary objective is to determine the effect of co-administration of telepravir, given as 2 tablets of 375 mg every 8 hours and DRV/rtv or fAPV/rtv on the amount of telaprevir and DRV/rtv or fAPV/rtv in the body. The secondary objective is to...

Ethical review	Approved WMO
Status	Pending
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON32330

Source
ToetsingOnline

Brief title
An interaction study of telaprevir in combination with DRV/rtv or fAPV/rtv

Condition

- Viral infectious disorders

Synonym
hepatitis C / liver disease

Research involving
Human

Sponsors and support

Primary sponsor: TIBOTEC PHARMACEUTICALS In Nederland vertegenwoordigd door Janssen-Cilag B.V. afdeling GCO
Source(s) of monetary or material Support: Janssen-Cilag,Tibotec BVBA

Intervention

Keyword: healthy subjects, hepatitis C, metabolic interaction, telaprevir

Outcome measures

Primary outcome

The primary objective is to determine the effect of co-administration of

telepravir, given as 2 tablets of 375 mg every 8 hours and DRV/rtv or fAPV/rtv

on the amount of telaprevir and DRV/rtv or fAPV/rtv in the body.

Secondary outcome

The secondary objective is to determine the effect of telaprevir and DRV/rtv or

fAPV/rtv on the amount of telaprevir and DRV/rtv and fAPV/rtv in the body when

telaprevir is taken as two tablets of 375 mg every 12 hours instead of the

regimen of two tablets every 8 hours. Additionally, the study wants to

investigate the short term safety and tolerability of the concomitant use of

telaprevir and DRV/rtv, as well as telaprevir and fAPV/rtv in healthy subjects.

Study description

Background summary

This new investigational drug called telaprevir is in process of development for the treatment of patients who are infected with hepatitis C virus (HCV). Telaprevir is a so-called "protease inhibitor", a new investigational class of

drugs that works by blocking an enzyme (called "protease") that the hepatitis C virus needs for its reproduction. Telaprevir is being studied for the treatment of hepatitis C in association with pegylated interferon and ribavirin, and the association of the three drugs may be more efficient at curing people than the standard combination alone.

Study objective

The primary objective is to determine the effect of co-administration of telepravir, given as 2 tablets of 375 mg every 8 hours and DRV/rtv or fAPV/rtv on the amount of telaprevir and DRV/rtv or fAPV/rtv in the body. The secondary objective is to determine the effect of telaprevir and DRV/rtv or fAPV/rtv on the amount of telaprevir and DRV/rtv and fAPV/rtv in the body when telaprevir is taken as two tablets of 375 mg every 12 hours instead of the regimen of two tablets every 8 hours. Additionally, the study wants to investigate the short term safety and tolerability of the concomitant use of telaprevir and DRV/rtv, as well as telaprevir and fAPV/rtv in healthy subjects.

Study design

Open label, randomised, cross-over trial

Study burden and risks

The risks of participation in this trial is associated with possible adverse events of telaprevir, DRV/rtv and fAPV/rtv. The burden for the participant is also associated with the admission to the unit, venapunction and insertion of canule. All subjects will be carefully followed on any adverse events and will be under the supervision of experienced physicians and study personnel.

Contacts

Public
TIBOTEC PHARMACEUTICALS In Nederland vertegenwoordigd door Janssen-Cilag B.V. afdeling GCO

Dr. Paul Janssenweg 150
5026 RH Tilburg
the Netherlands
Scientific
TIBOTEC PHARMACEUTICALS In Nederland vertegenwoordigd door Janssen-Cilag B.V. afdeling GCO

Dr. Paul Janssenweg 150

5026 RH Tilburg
the Netherlands

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-male or female aged between 18-55 year
-females should be amenorrheal for at least 3 years, or post-hystorectomy or post-tubal ligation
-nonsmoking or smoking no more than 10 cigarettes, or 2 cigars, or 2 pipes per day
-normal weight at screening (BMI 18-30 kg/m2)
-healthy based on the assessments performed at screening

Exclusion criteria

-subjects with a history of any illness that, in the opinion of the investigator or the subject*s general practitioner, might confound the results of the study or pose an additional risk in administering study drug(s) to the subject
-current use of prescription medication
-Regular treatment with over-the-counter medications. Subjects should stop over-the-counter medications on the date of the Screening Visit but no less than 7 days prior to the first administration of study medication
-consumption of herbal medication or dietary supplements and grapefruit and grapfruit juice, apple juice, orange juice within 14 days before first administration of studymedication
-consumption of more than 2 units alcoholic beverages per dag er 14 per week
-consumption of more an avarage of more than 5 servings of coffee or other caffeinated beverages per day
-a history of drug or alcohol abuse or addiction, or who test positive for alcohol or drugs such as cannabis, cocaine, amphetamines, benzodiazepines, or opiates during the screening period

-participation in a clinical study involving administration of an investigational drug within 3 months
-donation of any blood or having had a significant loss of blood within 3 months
-positive test for any of the following infectious disease tests: hepatitis A infection (confirmed by hepatitis A antibody IgM), hepatitis B antigen (HBsAg), hepatitis C virus antibody (HCVAb), human immunodeficiency virus 1 antibody (HIV1Ab), or human immunodeficiency virus 2 antibody (HIV2Ab)
-male subjects with female partners that are pregnant, or planning to become pregnant during the study or within 90 days of the last dose of study medication
-having participated previously in a trial with telaprevir (VX-950)

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	29-05-2008
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	NA
Generic name:	telaprevir
Product type:	Medicine
Brand name:	Prezista
Generic name:	duranivir
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	Ritonavir
Generic name:	Norvir
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Telzir
Generic name:	Fosamprenavir
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-05-2008
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	08-08-2008
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	EUCTR2008-002104-26-NL
CCMO	NL23172.072.08