A Phase 2 Study of Telaprevir (VX-950) in Combination with Peginterferon Alfa-2a (Pegasys??), and Ribavirin (Copegus??) in Subjects with Genotype 1 Hepatitis C Who Have Not Achieved Sustained Viral Response with a Prior Course of Interferon Based Therapy

Published: 05-03-2007
Last updated: 08-05-2024

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

Summary

ID

NL-OMON30460

Source
ToetsingOnline

Brief title
Prove 3

Condition

- Viral infectious disorders

Synonym
Hepatitis C, leverontsteking

Research involving
Human

Sponsors and support

Primary sponsor: Vertex Pharmaceuticals
Source(s) of monetary or material Support: Vertex Pharmaceuticals Incorporated

Intervention

Keyword: Hepatitis C, Telaprevir, Viral Respons

Outcome measures

Primary outcome

Undetectable HCV RNA 24 weeks after the completion of treatment

Secondary outcome

- Undetectable HCV RNA at end of treatment.

- Undetectable HCV RNA 48 weeks after completion of treatment (Groups B, C, and

D).

- Adverse events and clinical laboratory assessments, including ALT and other

liver function tests.

- Genotypic and phenotypic analyses of the NS3*4A HCV region.

- Pharmacokinetic assessments of telaprevir, Peg-IFN-a-2a, and RBV.

Study description

Background summary

Despite the significant advances that have been made in the treatment of chronic hepatitis C virus (HCV) infection in recent years, there is an ongoing need for effective treatment in patients who fail to achieve sustained virologic response (SVR). An antiviral drug such as telaprevir that could be administered in combination with direct or indirect-acting antivirals to produce a higher rate of viral eradication with a better safety profile and/or

shorter treatment duration is highly desirable.

Study objective

To compare to control (Group A) (peginterferon alfa-2a [Peg IFN-*-2a] and ribavirin [RBV] for 48 weeks) the proportion of subjects who achieve sustained viral response (SVR, undetectable HCV RNA 24 weeks after completion of treatment) when given telaprevir in combination with: Peg IFN-*-2a and RBV for 24 weeks followed by 24 weeks of Peg IFN-*-2a and RBV given alone (Group B); Peg IFN-*-2a for 24 weeks (Group C); Peg IFN-*-2a and RBV for 12 weeks followed by 12 weeks of Peg IFN-*-2a and RBV given alone (Group D).

Study design

Randomized, stratified, partially placebo-controlled, partially double-blind, study

Intervention

One dose regimen of telaprevir (oral tablet) will be used. A single loading dose of 1125 mg will be administered as the first dose of Day 1, followed by 750 mg q8h for the remainder of the treatment period. Peg-IFN-*-2a will be administered at a dosage of 180 µg/week by subcutaneous injection . RBV will be administered at a dosage of 1000 mg/day for subjects weighing * 75 kg and 1200 mg/day for subjects weighing >75 kg.
The four treatmentgroups will be treated with Peg-IFN-*-2a en RBV for the duration of their participation in the trial.
Group A will be treated with a pacebo instead of telaprevir. Group D will be treated with telaprevir form week 1 to week 12 and with with a placebo from week 12 to week 24.
Group A en B will be treated with Peg-IFN-*-2a en RBV only from week 24 to 48.

Study burden and risks

The subject will be treated with study medication for the duration of 48 weeks (Group A and B) or 24 weeks (Group C and D). During the treatment period will the subjects visit the hospital 20 times (group A and B) or 14 times (group C en D). If necessary additional visits can be scheduled by the investigator.
Two weeks after the last dose of study medication will the subject visit the hospital for a follow up visit (Is applicalbe to group A, B, C and D). After this visits will 1 to 4 additional visits be scheduled to check if the virus has returned. The number of visits will depend whether the virus has returned or not.
A full physical examiniation will be performed a number of times during the study. During every visits will blood be drawn.
The subject will be asked to complete a dosing sheet for the study medication.

The subject may experience adverse reactions while taking study medication.
Men and women must use an effective method of contraception as described in the study protocol.
The use of certain medication is allowed while the subject is participating in the trial. This medication is described in the study protocol.

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

- Male and female subjects, 18 to 70 years of age, inclusive.
- Genotype 1 (confirmed by standard testing), chronic hepatitis C. Chronic (non-acute) disease status must be confirmed by detectable plasma HCV RNA.
- Liver biopsy within 3 years of the date of the Screening Visit.
- Judged to be in good health on the basis of medical history and physical examination

(including vital signs and ECG), with any chronic medical conditions under stable medical control.
- Both Screening Visit 1 and Screening Visit 2 laboratory values must be within protocol specified laboratory reference ranges.
- Did not achieve SVR with at least 1 adequate prior course of Peg-IFN in combination with RBV (Peg-IFN/RBV) as defined by the protocol. Subjects must have received the last dose of Peg-IFN or RBV at least 12 weeks before the screening visit for this study.
- Must agree to use 2 methods of contraception that are highly effective, including one barrier method, during and for 24 weeks after the last dose of study drug (unless the subject is a woman of documented non-child-bearing potential). Female partners of male subjects must use the same precautions.
- Female subjects of child-bearing potential must have a negative pregnancy test at all visits (screening and predose Day 1) before the first dose of study drugs.
- Willing to refrain from the concomitant use of any medications, substances, or foods noted in Section 21.
- Able to read and understand the Informed Consent Form (ICF) and willing to sign the ICF and abide by the study restrictions.
- Agree not to participate in other clinical studies for the duration of his/her participation in this trial through antiviral follow-up.

Exclusion criteria

- Any medical contraindications to Peg-IFN or RBV therapy.
- Prior response to therapy and failure to achieve Sustained Viral Response which may have been due to treatment non-compliance, in the assessment of the investigator based upon subject*s medical history.
- Participation in any clinical trial of a HCV protease inhibitor of any duration.
- Participation in any clinical trial of an investigational drug within 90 days before drug administration or participation in more than 2 drug studies in the last 12 months (exclusive of the current study).
- History of or current evidence of decompensated liver disease defined as a prior or current history of ascites, hepatic encephalopathy, bleeding esophageal or gastric varices.
- Any other cause of significant liver disease in addition to hepatitis C; this may include but is not limited to, hepatitis B, drug or alcohol-related cirrhosis, autoimmune hepatitis, hemochromatosis, Wilson*s disease, nonalcoholic steatohepatitis, or primary biliary cirrhosis.
- Diagnosed or suspected hepatocellular carcinoma.
- Alcohol or drug abuse or excessive use (in the opinion of the investigator, as judged by medical history) in the last 12 months.
- Women who are pregnant or breast-feeding.
- Male partners of women who are pregnant or breast-feeding.
- Hypersensitivity to tartrazine (yellow dye #5).

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	24
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Copegus
Generic name:	Ribavirin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	niet van toepassing
Generic name:	Telaprevir
Product type:	Medicine
Brand name:	Pegasys
Generic name:	peginterferon alfa-2a
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	05-03-2007
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-05-2007
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2007
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-09-2007
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-11-2007
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-08-2008
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2006-004665-33-NL
CCMO	NL16173.018.07