Treatment adherence in patients treated with telaprevir for a chronic hepatitis C genotype 1 infection: an observational study

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Primary objective To establish the mean level of adherence to telaprevir in chronic hepatitis C patients during treatment with telaprevir, pegylated-interferon-alfa and ribavirin.Secondary objectives• To establish the mean level of adherence to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON39839

Source
ToetsingOnline

Brief title
treatment adherence telaprevir

Condition

- Hepatic and hepatobiliary disorders
- Viral infectious disorders

Synonym
hepatitis C

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Janssen-Cilag

Intervention

Keyword: chronic viral hepatitis, hepatitis C, infectious diseases, treatment adherence

Outcome measures

Primary outcome

treatment adherence measured by MEMScaps and questionaire

Secondary outcome

virological outcome (ie RVR/SVR)

plasma concentrations telaprevir/ ribavirine

outcome Hospital Anxiety and Depression scale questionnaire

Study description

Background summary

Chronic hepatitis C virus (HCV) infection is a major cause of cirrhosis. HCV is endemic in most parts of the world, and is estimated that at least 170 million people are or have been infected with HCV worldwide. Approximately 20%-30% of patients with chronic HCV infection will develop cirrhosis. Death related to the complications of cirrhosis occurs at an incidence of approximately 4% per year, whereas hepatocellular carcinoma (HCC) is detected in this population at a rate of 1-5% per year. HCV related end-stage liver disease is now the main indication for liver transplantation in the USA and Western Europe.
Hepatits C genotype 1 is responsible for most HCV infections in Europe, Asia and the United States. Treatment with pegylated-interferon-alfa and ribavirin (Peg/RBV) is only effective in 40%-50% of patients and associated with significant side effects. In several recent clinical trials, telaprevir, an orally bioavailable inhibitor of the nonstructural 3/4A HCV protease, substantially enhance rates of sustained virologic response when combined with peginterferon plus ribavirin in patients. In treatment-naïve patients rate of treatment success doubled in patients treated with pegylated-interferon-alfa, ribavirin and telaprevir to 72%. In 65% of patients treatment duration can be

shortened to 24 weeks instead of 48 weeks. The changes of treatment success decrease to 63% in patients with significant fibrosis and/or cirrhosis.
Adherence to Peg/RBV is essential since dose reductions and non-compliance are associated with a reduction of sustained viral response rates. It is likely that the addition of telaprevir to the current standard of care will be challenging for patients due to the need to take telaprevir with a fatty meal to achieve adequate plasma levels of telaprevir. It was previously shown that only about half of the patients who were prescribed a regimen with three times daily dosing together with dietary instructions for the treatment of HIV-1 infection were able to be fully adherent to such regimens.
Depression is a common side effect of treatment with Peg/RBV. Depression is one of the most important risk factors for having low levels of medication adherence. We therefore anticipate that depression could have a negative influence on the levels of adherence of patients who are treated with telaprevir and Peg/RBV.
The proposed study will establish to what extent patients who are receiving telaprevir and Peg/RBV in routine clinical practice are able to adhere to their treatment regimen. If the proposed study would yield low levels of adherence, this would suggest that additional adherence monitoring and support would be required in routine clinical practice.

Study objective

Primary objective

To establish the mean level of adherence to telaprevir in chronic hepatitis C patients during treatment with telaprevir, pegylated-interferon-alfa and ribavirin.

Secondary objectives
• To establish the mean level of adherence to ribavirin in chronic hepatitis C patients during treatment with pegylated-interferon-alfa and ribavirin following 12 weeks of treatment with telaprevir, pegylated-interferon-alpha and ribavirin.
• To explore the effects of different levels of adherence to telaprevir on the likelihood of achieving rapid virological response (RVR) and sustained virologic response.
• To explore the effects of different levels of adherence to ribavirin on the likelihood of achieving rapid virological response (RVR) and sustained virologic response.
• To assess changes in adherence to telaprevir and ribavirin over time.
• To assess telaprevir and ribavirin trough levels
• To explore the effects of telaprevir and ribavirin trough levels on the likelihood of achieving rapid virological response (RVR) and sustained virologic response.
• To investigate the association between adherence to telaprevir and ribavirin

and the presence of depression and anxiety symptoms

Study design

open label single arm observational study

Study burden and risks

none

Contacts

Public
Academisch Medisch Centrum

meibergdreef 9
amsterdam 1105az
NL
Scientific
Academisch Medisch Centrum

meibergdreef 9
amsterdam 1105az
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age 18 to 70 years
- BMI 18-38 kg/m2
- Treatment-naïve for HCV, virological relapse or partial virological response (> 2log10 decline at week 12) after previous treatment with peg/RBV
- HCV genotype 1a or 1b
- Clinical and laboratory findings consistent with a clinical diagnosis of chronic hepatitis C
- Serum HCV RNA >10.000 IU/mL at baseline

Exclusion criteria

History or symptoms of decompensated liver disease: Child-Pugh Class B or C, including ascites, hepatic encephalopathy, esophageal variceal bleeding or other signs of hepatic insufficiency or portal hypertension ;Positive results on the following screening laboratory tests: urine or serum pregnancy test (for women of childbearing potential), hepatitis B surface antigen and human immunodeficiency virus (HIV) antibody.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-05-2013
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	12-11-2012
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-04-2013
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
CCMO	NL41955.018.12