Long term clinical outcome of treatment for chronic hepatitis C in patients with advanced fibrosis

Published: 23-03-2010
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The aim of this study is to determine the clinical benefit of effective antiviral treatment in patients with advanced fibrosis due to chronic hepatitis C infection.

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

Summary

ID

NL-OMON34894

Source
ToetsingOnline

Brief title
outcome of therapy for HCV in advanced fibrosis

Condition

- Hepatic and hepatobiliary disorders
- Viral infectious disorders
- Hepatobiliary therapeutic procedures

Synonym
chronic liver disease, chronic viral hepatitis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Lever Onderzoek (SLO)

Intervention

Keyword: advanced fibrosis, antiviral therapy, clinical outcome, hepatitis C

Outcome measures

Primary outcome

- hepatcellular carcinoma

- liver failure: Ascites/encephalopathy/jaundice/variceal bleed

- death

- new onset Diabetes Mellitus

Secondary outcome

- Biochemical results:

ALT/AST/albumin/bilirubin/creatinine/glucose/insulin/HbA1c

- Hemological results: platelet count/prothrombin time

- Virology: viral load

- Ultrasound: spleen size

- Fibroscan results: liver stiffness

Study description

Background summary

The hepatitis C virus can chronically infect the liver, often leading to liver damage (liver fibrosis). Treatment in an early stage is preferred since successful eradication of the virus can stop the progression to advanced liver fibrosis, or even cirrhosis. Liver cirrhosis can be complicated by liver failure and/or liver cancer. It is recommended that cirrhotic patients have regular control visits in the hospital, so early treatment of complications is possible.

Liver cirrhosis is considered to be an irreversible condition of the liver. Even after being cured from the hepatitis C infection, cirrhotic patient are

still at risk for the complications.
Currently there is some evidence that the risk of complications decreases when the virus is eradicated in patients with advanced liver fibrosis, however to what extend is still uncertain.
The disadvantages of the treatment for chronic hepatitis C are well known, and involve adverse events, long treatment duration and a limited chance of success. In all medical treatments the advantages should outweigh the disadvantages, and so it is of great importance to have more extensive knowledge of the benefits of antiviral treatment in hepatic C patients with advanced fibrosis.

Study objective

The aim of this study is to determine the clinical benefit of effective antiviral treatment in patients with advanced fibrosis due to chronic hepatitis C infection.

Study design

Retrospective Follow-up study.
Patients with incomplete follow-up data will be contacted in order to obtain recent data concerning their current health status.

Study burden and risks

Patients with incomplete follow-up data will be invited to visit the outpatient clinic of the researchcenter once. During this visit a routine check-up of patients with advanced liver disease will be performed, consisting of a medical history, blood tests and abdominal ultrasound. The time-investment is approximately 1.5 hours and the participants will have a low risk of hematomas due to venipuncture for the collection of bloodsamples.

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

- history of chronic Hepatitis C
- Interferon based antiviral treatment for chronic hepatitis C between 1990 en 2003
- biopsy-proven advanced liver fibrosis (metavir score F3-F4)

Exclusion criteria

- HIV infection
- chronic hepatitis B infection
- secondary liver disease

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-09-2010
Enrollment:	64
Type:	Actual

Ethics review

Approved WMO

Date:	23-03-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL30917.078.10