Management and treatment of patients with a (previous) substance dependency and/or marginally housed patients with chronic hepatitis C: a prospective observational registry

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To register the feasibility of treatment with peginterferon and ribavirin for chronic hepatitis C in (previous) substance users and other difficult to treat patients within the Project Active Testing.

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

Summary

ID

NL-OMON33839

Source
ToetsingOnline

Brief title
Fase 3 Project Active Testing.

Condition

- Hepatic and hepatobiliary disorders
- Viral infectious disorders
- Lifestyle issues

Synonym
HCV infection, Hepatitis C

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Gemeente Rotterdam,Schering-Plough

Intervention

Keyword: Compliance, Feasibillity, HCV, Substance dependency

Outcome measures

Primary outcome

Primary objective:

· SVR

· Compliance to therapy

This data is obtained from project active testing phase 3.

Secondary outcome

Secondary objective:

· Safety: infectious, psychiatric and serious adverse events (phase 3)

· Quality of life and psychopathology by psychological assessment using SF-36

and SCL-90 questionnaires (phase 3)

· Effect of alcohol use on adherence and success rate (phase 3)

· Epidemiology: Prevalence of hepatitis C and HIV in this group (phase 1 & 2)

· Evaluate the Project Active Testing (phase 1,2 and 3)

o Percentages of successful screening, diagnosis/staging and treatment of

chronic hepatitis C

o Effect of social support and professional care

o Cost-effectiveness

o Degree of liver fibrosis

Study description

Background summary

The treatment of chronic hepatitis C with peginterferon and ribavirin is highly effective but is hampered by side effects like flu-like symtpoms and peginterferon-induced psychopathology. Compliance to therapy is of major importance in achieving a good clinical outcome of treatment (sustained virological respons)(1-4). For these reasons patients with a current or recent history of substance abuse and/or other social and health concerns like homelessness were excluded for therapy in the past. However there is growing evidence in literature from previous studies that treatment with peginterferon and ribavirin can be safe and effective in this group of patients. In these studies several models for optimum HCV treatment delivery were developed in multidisciplinary teams. (5-8)
As a result, the National Institutes of Health (NIH) consensus statement recommended in 2002 that individuals with active injection drug use could be considered for HCV treatment. These recommendations were reinforced by the most recent practice guidelines of the American Association for the Study of Liver Disease.(9,10)

The aim of Project Active Testing is to stimulate HIV, HBV and HCV testing, and if necessary treatment or vaccination of (former) drug users and homeless groups. It focuses on close cooperation between the different organizations offering help to the patient group mentioned above and the treating physician in the (academic) hospital in order to lower barriers in the treatment of chronic hepatitis C in this patient group. In this project nurses in different organizations in the care for patients with substance abuse and social work are trained to get clients motivated to get tested for hepatitis C (and HIV), and if necessary motivate and accompany patients during their therapy.

The Project is divided in three different phases:
Phase 1:
· pre- and post test counseling
Phase 2:
· Medical: staging liver disease: indication treatment
· Social-economical: further education, evaluation and (if possible) solving problems that hinder treatment
· Final decision treatment
Phase 3:
· Professional care and social support during treatment: medication log, stop registration, evaluation substance abuse etc.

The Project Active Testing further enables the opportunity to start treatment in this *difficult-to-treat-population* within a structured and professional healthcare system.

Study objective

To register the feasibility of treatment with peginterferon and ribavirin for chronic hepatitis C in (previous) substance users and other difficult to treat patients within the Project Active Testing.

Study design

This is a multicentre prospective observational registry from the Foundation for Liver Research at the department of Gastroenterology & Hepatology of the Erasmus MC, Rotterdam, the Netherlands in cooperation with the Municipal Public Health Service.Rotterdam-Rijnmond.

Prospective observational registry with 80 patients receiving standard dosing of peginterferon alfa-2b (Pegintronâ) and ribavirin (Rebetolâ twice daily).

REGISTRY TIMELINE
Start patient entry : 15-05-2008
End patient entry : 15-11-2009
End of treatment : 15-10-2010
End of registry : 15-04-2011

REGISTRY DURATION
Treatment will start on day 0 for 24 or 48 weeks depending on genotype and virological response to treatment. Two follow-up visits are scheduled 4 weeks and 24 weeks after the end of treatment.

Study burden and risks

For this specific patientpopulation treatment with proper counselling is made possible.

Contacts

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Scientific
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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 patients between 18-70 years of age
Evidence of chronic hepatitis C by detectable serum HCV-RNA
Indication for antiviral therapy of hepatitis C according to current clinical guidelines
Adequate contraception

Exclusion criteria

- Other significant medical illness that might interfere with this study.
- Hepatocellular carcinoma
- History of thyroid disease poorly controlled on prescribed medications.
- Severe uncontrolled psychiatric disease.
- Any other condition which in the opinion of the registrator would make the patient unsuitable for enrollment, or could interfere with the patient participating in and completing the therapy.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-06-2008
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

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	NL22517.078.08