Interferon induction followed by PEG-interferon combined with ribavirin and amantadine for treatment of naive chronic hepatitis C patients with genotype 1 or 4.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27278

Source
Nationaal Trial Register

Brief title
VKF3

Health condition

chronic hepatitis C

Sponsors and support

Primary sponsor: AMC Liver Center, Department GastroAcademic Medical Center, University of Amsterdam
Source(s) of monetary or material Support: Schering-Plough
Academic Medical Center, University of Amsterdam

Intervention

Outcome measures

Primary outcome

Sustained virological response (HCV RNA undetectable 24 weeks after cessation of treatment).

Secondary outcome

Early viral kinetics vs outcome
immunological parameters during treatment (correlation with outcome) liver fibrosis before and after Rx.

Study description

Background summary

In this study previously untreated patients with chronic hepatitis C will receive high induction dose of IFN combined with Ribavirin and Amantadine for 6 weeks. Subsequently IFN is replaced by Peg IFN combined with Ribavirin and Amantadine.
The aim of the study is to determine with the above treatment schedule, if a higher SVR rate can be achieved in patients with genotype 1 or 4 and to establish if the drop in viral load in the first 4 weeks of treatment is predictive for SVR.

Study objective

In this study previously untreated patients with chronic hepatitis C will receive high induction dose of IFN combined with Ribavirin and Amantadine for 6 weeks. Subsequently IFN is replaced by Peg IFN combined with Ribavirin and Amantadine.
The aim of the study is to determine with the above treatment schedule, if a higher SVR rate can be achieved in patients with genotype 1 or 4 and to establish if the drop in viral load in the first 4 weeks of treatment is predictive for SVR.

Study design

N/A

Intervention

All patients will be treated for 24 or 48 weeks. Patients who achieve a 3log drop in viral load after 4 weeks of treatment will be randomized to stop treatment early after 24 weeks or continue to 48 weeks. Patients who do not achieve a 3 log drop after 4 weeks of treatment will be treated for 48 weeks. Patients who are HCV RNA positive at week 24 will stop

treatment.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients which are serum HCV-RNA positive by PCR and with genotype 1 or 4;

2. Patients who never have used antiviral therapy for chronic hepatitis C;

3. Male and female patients >= 18 and < 65 years of age;

4. Patients who have given written informed consent after a detailed explanation of the study by the investigator.

Exclusion criteria

1. Patients who are pregnant and patients (male or female) who are not willing to practice adequate contraception during the treatment period and up to 6 months after ending the treatment period;

2. Patients who are HBsAg or HIV antibody positive or who are unwilling to have these tests done;

3. Patients with decompensated cirrhosis (e.g. albumin < 32g/L, PTT prolonged > 4 s, bilirubin 2x > upper limit of normal, AT III < 60%, ascites, GI bleeding, encephalopathy);

4. Patients with a history of i.v. drug use within 6 months prior to entry;

5. Patients with any clinically significant systemic disease other than liver disease (e.g. malignant disease, congestive heart failure, uncontrolled diabetes mellitus, renal failure (serum creatinine > 181 micromol/ml), or autoimmmune disease;

6. Patients with a history of auto-immune hepatitis;

7. Patients using immune modulating treatment during the 6 months prior to study entry;

8. Patients with a history of hypersensitivity to any component of the study drugs;

9. Patients with pre-existing bone marrow depression such as hematocrit < 32%, white blood cell count < 3.0x10E9/L, granulocytes < 1.5x10E9/L, platelets < 100x10E9/L neutrophil count < 1.5x10E9 or Hemoglobin < 8.1 mmol/L for males and < 7.0 mmol/L for females;

10. Patients with severe depression or other psychiatric illness;

11. Patients with a history of epilepsy, or other clinically significant CNS dysfunction;

12. Patients with any condition, that in the opinion of the investigator, might interfere with the outcome of the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2002
Enrollment:	58
Type:	Actual

Ethics review

Positive opinion Date:	04-01-2006
Application type:	First submission

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
NTR-new	NL517
NTR-old	NTR560
Other	: N/A
ISRCTN	ISRCTN59358441

Study results

Summary results
N/A