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

Gepubliceerd: 04-01-2006 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27278

Bron
NTR

Verkorte titel
VKF3

Aandoening

chronic hepatitis C

Ondersteuning

Primaire sponsor: AMC Liver Center, Department GastroAcademic Medical Center, University of Amsterdam
Overige ondersteuning: Schering-Plough
Academic Medical Center, University of Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2002
Aantal proefpersonen:	58
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	04-01-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL517
NTR-old	NTR560
Ander register	: N/A
ISRCTN	ISRCTN59358441

Resultaten

Samenvatting resultaten

N/A