Study on chronic hepatitis Ctreatment with interferon alpha, ribavirin and amantadine in naive patients.

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Adding amantadine to the standard anti-HCV treatment can improve sustained response rates in chronic hepatitis C.

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

Samenvatting

ID

NL-OMON20761

Bron
NTR

Verkorte titel
CIRA-study

Aandoening

Chronic hepatitis C

Ondersteuning

Primaire sponsor: Dr. K.J. van Erpecum, hoofdonderzoeker
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Virological response at week 52 and 104.

Toelichting onderzoek

Achtergrond van het onderzoek

This is a double blind, placebo controlled, randomised, multicentre study in previously untreated patients suffering from chronic hepatitis C comparing double therapy, consisting of interferon alpha 2b (Intron-A®) and ribavirin (Rebetol®), with triple therapy, consisting of interferon alpha 2b, ribavirin and amantadine, for 52 weeks. Follow-up is completed at week 104.
150 subjects per treatment group will be included. Patients will be stratified before randomisation according to genotype (1 versus non-1).
Viral load will not be a discriminating factor.

The aim is to investigate the efficacy of the adjunct amantadine to the currently used combination therapy with interferon alpha and ribavirin.

Doel van het onderzoek

Adding amantadine to the standard anti-HCV treatment can improve sustained response rates in chronic hepatitis C.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

One year treatment with interferon/ribavirin and amantadine or placebo.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Anti-HCV positivity; >6 months;

2. ALT and/or AST elevation on at least once in the previous 6 months;

3. Positive HCV-RNA;

4. Liver biopsy within one year before the start of therapy in non-cirrhosis;

In the case of known cirrhosis, liver biopsy is not necessary;

5. Intention to be treated and participate treatment;

6. Obtained written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age < 18 years;

2. Pregnancy or intention to get pregnant within the 12 months period of treatment and up to 6 months after discontinuation of therapy, no adequate contraception, lactation;

3. Men not practicing or willing to practice acceptable methods of contraception during the treatment period and up to 6 months after discontinuation of therapy;

4. Life expectancy < 1 year;

5. Child Pugh B or C (Appendix III);

6. Creatinine > 150 ìmol/L or > 1.70 mg/dl;

7. Haemoglobulin < 6.5 mmol/l or < 10.5 g/dl, white blood cell count < 2,5 x 109/L, neutrophil < 1,5 x 109/L, platelet count < 70 x 109/L;

8. HIV positivity;

9. Chemotherapy, systemical antiviral treatment during the 6 months prior to study entry;

10. Other serious disease (e.g. malignancy, uncontrolled myocardial disease or severe arythmias);

11. Active uncontrolled psychiatric disorders and suicidal leanings;

12. Patients with a history of uncontrolled seizure or other significant CNS dysfunction;

13. Any condition which in the opinion of the (co-)investigator might interfere with the evaluation of the study objectives.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	14-02-2000
Aantal proefpersonen:	390
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	25-08-2005
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	NL114
NTR-old	NTR145
Ander register	: N/A
ISRCTN	ISRCTN74271466

Resultaten

Samenvatting resultaten
N/A