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

No registrations found.

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

Summary

ID

NL-OMON20761

Source
NTR

Brief title
CIRA-study

Health condition

Chronic hepatitis C

Sponsors and support

Primary sponsor: Dr. K.J. van Erpecum, hoofdonderzoeker
Prof. Dr. M. Samsom, hoofdonderzoker
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Intervention

Outcome measures

Primary outcome

Virological response at week 52 and 104.

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

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

Study design

N/A

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2000
Enrollment:	390
Type:	Actual

Ethics review

Positive opinion

Date:	25-08-2005
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	NL114
NTR-old	NTR145
Other	: N/A
ISRCTN	ISRCTN74271466

Study results

Summary results
N/A