

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

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/11/2008	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR145

Study information

Scientific Title

Acronym

CIRA-study

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Multicentre, randomised, double-blind, placebo-controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Hepatitis C

Interventions

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

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Amantadine, interferon/ribavirin

Primary outcome measure

Virological response at week 52 and 104.

Secondary outcome measures

No secondary outcome measures

Overall study start date

14/02/2000

Completion date

01/05/2007

Eligibility**Key inclusion criteria**

1. Anti-HCV positivity; greater than 6 months
2. Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) elevation on at least once in the previous 6 months
3. Positive hepatitis C virus ribonucleic acid (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

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

390

Key exclusion criteria

1. Aged less than 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 less than 1 year
5. Child Pugh B or C (Appendix III)
6. Creatinine greater than 150 $\mu\text{mol/L}$ or greater than 170 mg/dl
7. Haemoglobin less than 65 mmol/l or less than 105 g/dl, white blood cell count less than $2.5 \times 10^9/\text{L}$, neutrophil less than $1.5 \times 10^9/\text{L}$, platelet count less than $70 \times 10^9/\text{L}$
8. Human immunodeficiency virus (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

arrhythmias)

11. Active uncontrolled psychiatric disorders and suicidal leanings

12. Patients with a history of uncontrolled seizure or other significant central nervous system (CNS) dysfunction

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

Date of first enrolment

14/02/2000

Date of final enrolment

01/05/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Centre Utrecht (UMCU)

Utrecht

Netherlands

3508 GA

Sponsor information

Organisation

University Medical Centre Utrecht (UMCU) (Netherlands)

Sponsor details

PO Box 85500

Utrecht

Netherlands

3508 GA

Sponsor type

University/education

Website

<http://www.umcutrecht.nl/zorg/>

ROR

<https://ror.org/04pp8hn57>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration