ISRCTN74271466 https://doi.org/10.1186/ISRCTN74271466

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

Submission date	Recruitment status	[_] Prospectively registered
20/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/11/2008	Infections and Infestations	[_] 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 acide (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 µmol/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 x 10^9/L, neutrophil less than 1.5 x 10^9/L, platelet count less than 70 x 10^9/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
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3508 GA

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (Netherlands)

Sponsor details
PO Box 85500
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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