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

Submission date
04/04/2006

Recruitment status
No longer recruiting

Registration date
04/04/2006

Overall study status
Completed

Last Edited
17/08/2009

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Huub Gelderblom

Contact details
Academic Medical Center (AMC)
Department of Gastroenterology
AMC Liver Center
C2-331
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 5668748
h.c.gelderblom@amc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR560

Study information

Scientific Title

Acronym
VKF3

Study objectives
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 sustained virological response (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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Multicentre randomised open label active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Hepatitis C virus (HCV)

Interventions
All patients will be treated for 24 or 48 weeks. Patients who achieve a 3 log 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.

Intervention Type
Other

Phase
Not Specified

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

Secondary outcome measures
1. Early viral kinetics versus outcome
2. Immunological parameters during treatment (correlation with outcome)
3. Liver fibrosis before and after Rx

Overall study start date
01/07/2002

Completion date
01/01/2007

Eligibility

Key inclusion criteria
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

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
58

Key exclusion criteria
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 human immunodeficiency virus (HIV) antibody positive or who are unwilling to have these tests done

3. Patients with decompensated cirrhosis (e.g. albumin <32 g/l, PTT prolonged >4 s, bilirubin 2 x upper limit of normal, AT III <60%, ascites, gastrointestinal [GI] bleeding, encephalopathy)
4. Patients with a history of intravenous (iv) 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 µmol/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 <3.0 x 10^9/l, granulocytes <1.5 x 10^9/l, platelets <100 x 10^9/l, neutrophil count <1.5 x 10^9 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 central nervous system (CNS) dysfunction
12. Patients with any condition, that in the opinion of the investigator, might interfere with the outcome of the study

Date of first enrolment
01/07/2002

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
Department of Gastroenterology,
AMC Liver Centre
P.O. Box 22660

Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (Netherlands)

Funder Name
Schering-Plough (Netherlands)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/07/2009		Yes	No