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Combination therapy using pegylated interferon alfa-2a and ribavirin in patients with chronic hepatitis C virus (HCV) infection 3 to 120 months after liver transplantation

Submission date 05/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/09/2005	**Overall study status** Completed	
Last Edited 07/11/2008	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Michael P Manns

Contact details
Medizinische Hochschule Hannover
Dept. for Gastroenterology, Hepatology, and Endocrinology
Carl-Neuberg-Str. 1
Hannover
Germany
30625
+49 511 5323306
manns.michael@mh-hannover.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MHH-GHE- 3298

Study information

Scientific Title

Acronym
GIHALT Study

Study objectives
Currently, only retrospective reports on the use of pegylated interferon and ribavirin after liver transplantation are available. The study aims to evaluate efficacy and safety of this approach in a prospective, controlled, multi-center protocol.

Please note that, as of 05/11/2008, the end date of this trial has been updated from 31/12/2008 to 23/09/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Ethics Committee of the Hannover Medical School (Ethik-Kommission der Medizinische Hochschule Hannover) on the 6th of November 2003 (ref: 3298)

Study design
Randomised controlled 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 reinfection after liver transplantation

Interventions
Administration of pegylated interferon alfa-2a plus ribavirin versus no therapy.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Pegylated interferon alfa-2a and ribavirin

Primary outcome measure
Sustained viral clearance (HCV RNA negative, 24 weeks after the end of treatment).

Secondary outcome measures
1. Biochemical response (normal alanine aminotransferase [ALT], 24 weeks after the end of treatment)
2. On treatment virological response (HCV RNA negative after 12, 24, 48 weeks)
3. On treatment biochemical response (ALT normal after 12, 24, 48 weeks)
4. Histological response (24 weeks after the end of treatment)

Overall study start date
01/05/2004

Completion date
23/09/2008

Eligibility

Key inclusion criteria
1. Males, females above the age of 18
2. HCV reinfection after liver transplantation
3. 3 to 120 months after liver transplantation
4. Histology showing hepatitis
5. Negative pregnancy test
6. Willingness to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
75

Key exclusion criteria

1. Histology showing acute or chronic rejection
2. Hypersensivity to ribavirin, interferon
3. HCV-positive donor
4. Pretreatment with pegylated interferon plus/minus ribavirin
5. Pretreatment with interferon plus ribavirin
6. Pregnancy
7. Active cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis A virus (HAV) infection
8. Liver cirrhosis, Child Pugh stages B or C
9. Alpha fetoprotein >100 ng/m
10. Bilirubin >3.0 mg/d
11. Creatinine clearance <40 ml/min
12. Hemoglobin <10 g/dl (females), <11 g/dl (males)
13. Hepatocellular carcinoma within 2 months prior to randomization
14. Neutrophils <1500/µl
15. Leukozytes >11,000/µl
16. Platelets <75,000/µl
17. Patients at special risk for anemia
18. Patients at special risk for complications induced by anemia
19. Autoimmune disease
20. Functionally relevant chronic lung disease
21. Severe cardiovascular disease
22. Psychiatric disease, especially depression
23. Epilepsy
24. Carcinoma
25. Difficult to treat thyroid disease
26. Retinopathy
27. Difficult to treat diabetes mellitus
28. Active drug abuse, including alcohol abuse

Date of first enrolment
01/05/2004

Date of final enrolment
23/09/2008

Locations

Countries of recruitment
Germany

Study participating centre
Medizinische Hochschule Hannover
Hannover
Germany
30625

Sponsor information

Organisation
Hannover Medical School (Medizinische Hochschule Hannover) (Germany)

Sponsor details
Dept. for Gstroenterology, Hepatology, and Endocrinology
Carl-Neuberg-Str. 1
Hannover
Germany
30625

Sponsor type
University/education

Website
http://www.mh-hannover.de/index.php?id=2&L=1

ROR
https://ror.org/00f2yqf98

Funder(s)

Funder type
University/education

Funder Name
Hannover Medical School (Medizinische Hochschule Hannover) (Germany)

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