

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	<input type="checkbox"/> Prospectively registered
Registration date 09/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/11/2008	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

Contact name

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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. Hypersensitivity 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/ml
10. Bilirubin >3.0 mg/dl
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/ μ l
15. Leukozytes >11,000/ μ l
16. Platelets <75,000/ μ l
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 Gastroenterology, 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