

Treatment of acute hepatitis C infection: immediate therapy of all patients with peg-interferon alpha-2b alone versus delayed therapy of patients not eliminating hepatitis C virus (HCV) spontaneously with peg-interferon alpha-2b plus ribavirin

Submission date 03/08/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 09/09/2005	Overall study status Completed	☐ Protocol
Last Edited 08/11/2013	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

Study information

Scientific Title

Acronym

HCV III study

Study objectives

Efficacy of immediate therapy of acute hepatitis C infection is comparable to the efficacy of delayed therapy of patients that do not eliminate HCV spontaneously.

Please note that, as of 07/11/2008, the anticipated end date of this trial has been updated from 31/12/2007 to 31/12/2010.

Please note that, as of 24/01/2012, the anticipated end date of this trial has been updated from 31/12/2010 to 31/12/2011.

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 22/08/2003 (ref: 3272)

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute hepatitis C

Interventions

Please note that as of 08/11/10 the end date of this trial has been extended from 31/12/10 to 31/12/11. Recruitment finished in 09/09/10

Administration of peg-interferon alpha-2b subcutaneously (sc) versus administration of peg-interferon alpha-2b plus ribavirin orally (po) for 24 weeks

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

peg-interferon alpha-2b and ribavirin

Primary outcome(s)

HCV virological response (HCV RNA negative) 84 weeks after randomisation or 24 weeks after the end of treatment

Key secondary outcome(s)

1. Biochemical response (alanine aminotransferase [ALT] and aspartate aminotransferase [AST] levels)
2. Severity and frequency of adverse events
3. Rate of spontaneous clearance of HCV
4. Quality of life during acute HCV infection and during treatment
5. Evaluation of HCV-specific CD4+ and CD8+ T cell responses and humoral immune responses

Completion date

31/12/2011

Eligibility

Key inclusion criteria

1. Patients with acute HCV infection and detectable HCV RNA
2. More than 18 years
3. Compensated liver disease
4. Negative urine or blood pregnancy test
5. Willingness to give written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Other possible reasons for acute HCV infection
2. Liver cirrhosis
3. Pregnancy or breast feeding
4. Previous antiviral therapy with interferon or ribavirin
5. Positive test results for anti hepatitis A virus (HAV) IgM antib., HBsAg, anti-HBc IgM antib.,

HBeAg, anti human immunodeficiency virus (HIV)

6. History or evidence for chronic liver disease

7. History of severe psychiatric disease, thyroid dysfunction poorly controlled

8. History or evidence for severe illness

9. Drug use within 6 months prior to first dose of study drug

Date of first enrolment

01/04/2004

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

Germany

Study participating centre

Medizinische Hochschule Hannover

Hannover

Germany

30625

Sponsor information

Organisation

Hannover Medical School (Medizinische Hochschule Hannover) (Germany)

ROR

<https://ror.org/00f2yqf98>

Funder(s)

Funder type

Government

Funder Name

Federal Ministry of Education and Research, network of competence for hepatitis (Kompetenznetz Hepatitis; http://www.kompetenznetz-hepatitis.de/about-hep-net/about-hep-net?set_language=en), c/o Hannover Medical School (Medizinische Hochschule Hannover) (Germany).

Results and Publications

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	01/06/2013		Yes	No