

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 | <input type="checkbox"/> Prospectively registered |
| Registration date 09/09/2005 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 08/11/2013 | Condition category Infections and Infestations | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

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 (0)511 5323306
manns.michael@mh-hannover.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3272

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)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/04/2004

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

135 (as of 08/11/10, previously: 150) (Recruitment completed, last patient visit on 27/09/2011).

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)

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

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

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 | 01/06/2013 | | Yes | No |