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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 mionths 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