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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

**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)

### Study design
Randomised controlled trial

### Primary study design
Interventional

### 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 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)

### 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |