

Comparison of Three Regimens of PEG-Intron plus Ribavirin in the Treatment of Chronic Hepatitis C, Genotype 2 or 3, in Previously Untreated Patients

Submission date
02/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
26/09/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
12/01/2021

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.kompetenznetz-hepatitis.de/en/study_house/redd_en.htm

Contact information

Type(s)

Scientific

Contact name

Prof Michael P. Manns

Contact details

Medizinische Hochschule Hannover

Director of the Department for Gastroenterology, Hepatology, and Endocrinology

Carl-Neuberg-Str. 1

Hannover

Germany

30625

+49 (0)5115323305

manns.michael@mh-hannover.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00302081

Secondary identifying numbers
3272

Study information

Scientific Title

Comparison of Three Regimens of PEG-Intron plus Ribavirin in the Treatment of Chronic Hepatitis C, Genotype 2 or 3, in Previously Untreated Patients

Acronym

Redd 2-3 Study (Reduction of dose and duration)

Study objectives

Non-Inferiority of lower dosage with 1.0 µg/kg PEG-Intron in comparison to the standard treatment with 1.5 µg/kg PEG-Intron and non-inferiority of shorter treatment duration of 16 weeks in comparison to the standard treatment with a duration of 24 weeks.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

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

Health condition(s) or problem(s) studied

Chronic hepatitis C of genotype 2 or 3

Interventions

Application of:

- a. 1.5 µg/kg Peg-Interferon alpha-2b subcutaneously (sc) + 800-1200 mg ribavirin orally (po) weight adapted for 24 weeks
- b. 1.0 µg/kg Peg-Interferon alpha-2b sc + 800-1200 mg ribavirin po weight adapted for 24 weeks
- c. 1.5 µg/kg Peg-Interferon alpha-2b sc + 800-1200 mg ribavirin po weight adapted for 16 weeks

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

PEG-Intron and Ribavirin

Primary outcome measure

Sustained HCV-virological response (HCV-RNA negative in serum by a standard HCV-PCR with a detection limit of at least 600 IU/ml) 24 weeks after the end of treatment.

Secondary outcome measures

Virological response rates (HCV-RNA negative in serum by a standard HCV-PCR with a detection limit of at least 600 IU/ml) at the end of therapy; biochemical responses as determined by ALT and AST levels at the end of treatment and at the end of follow up; severity and frequency of adverse events; quality of life (assessed by SF-36).

Overall study start date

01/05/2003

Completion date

31/12/2006

Eligibility

Key inclusion criteria

Haemoglobin >12 g/kl (females); >13 g/kl (males); Platelet count >100,000/mm³; Neutrophil count >1500/mm³; Adult male or female chronic hepatitis C (CHC) patients (HCV-RNA-positive in serum) with compensated liver disease (Child-Pugh Score <7) and indication for treatment according on current consensus guidelines (1. NIH Consensus Conference on the Management of Hepatitis C, 2002; 2. German Consensus Conference on Hepatitis B and C, Z Gastro 2004); >18 to <70 years of age; at least one abnormal ALT value in the last year; HCV genotype 2 or 3; not previously treated with any interferon or ribavirin alone or in combination; TSH level within normal limits; Women of childbearing potential: negative pregnancy test performed at baseline; Sexually active female subjects of childbearing potential: adequate contraception or monogamous relationship with a male partner who has had a vasectomy or is using a condom (+ spermicide) during the treatment period and for seven months after stopping treatment; Sexually active male subjects: acceptable methods of contraception (vasectomy, use of condom + spermicide, monogamous relationship with a female partner who practices an acceptable method of contraception) during the treatment period and for seven months after stopping treatment; written informed consent.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

670

Total final enrolment

682

Key exclusion criteria

Patients younger than 18 years; Patients older than 70 years of age; Anti-human immunodeficiency virus (HIV) positivity; HBsAg-positivity; existence of, or a history of severe psychiatric condition, particularly severe depression, suicidal ideation of suicide attempt; Autoimmune hepatitis; or history of autoimmune disease; patients with severe renal dysfunction or creatinine clearance <50 ml/min; active drug abuse.

Date of first enrolment

01/05/2003

Date of final enrolment

31/12/2006

Locations**Countries of recruitment**

Germany

Study participating centre

Medizinische Hochschule Hannover

Hannover

Germany

30625

Sponsor information**Organisation**

Medical University Hannover (Medizinische Hochschule Hannover), Kompetenznetz Hepatitis (Germany)

Sponsor details

Department for Gastroenterology, Hepatology, and Endocrinology
Carl-Neuberg-Str. 1
Hannover
Germany
30625
+49 (0)5115326815
hep-net@mh-hannover.de

Sponsor type

University/education

Website

<http://www.kompetenznetz-hepatitis.de>

ROR

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

Funder(s)

Funder type

University/education

Funder Name

Medical University Hannover (Medizinische Hochschule Hannover)

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	01/09/2011	12/01/2021	Yes	No

