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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	Recruitment status	[_] Prospectively registered
02/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/01/2021	Infections and Infestations	

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

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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/mm^3; Neutrophil count >1500/mm^3; 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)

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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