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Retreatment of hepatitis C non-responsive to Interferon: a placebo controlled randomised trial of Ribavirin monotherapy versus combination therapy with Ribavirin and Interferon in 121 patients in the Benelux

Submission date 30/07/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/08/2003	**Overall study status** Completed	
Last Edited 05/09/2007	**Condition category** 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
N/A

Study information

Scientific Title

Acronym
Retreatment of hepatitis C non-responsive to Interferon.

Study objectives
Not provided at time of registration

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

Interventions
Patients were randomised to:
1. 6 months combination therapy with interferon alpha-2b (3 MU tiw) and ribavirin (1000 - 1200 mg / day)
2. 6 months ribavirin monotherapy (1000 - 1200 mg / day)
3. 6 months ribavirin placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ribavirin monotherapy, Ribavirin and Interferon combination

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1992

Completion date
01/01/1996

Eligibility

Key inclusion criteria
Patients with chronic hepatitis C and elevated transaminases who did not respond to previous treatment with standard interferon monotherapy.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
117

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1992

Date of final enrolment
01/01/1996

Locations

Countries of recruitment
Belgium

Netherlands

Study participating centre
Dr. Molewaterplein 40
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Sponsor information

Organisation
Schering Plough International (USA)

Sponsor details
c/o Janice K. Albrecht
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Sponsor type
Industry

Website
http://www.schering.com/

ROR
https://ror.org/02891sr49

Funder(s)

Funder type
Research organisation

Funder Name
Foundation for Liver Research in Rotterdam (The Netherlands)

Funder Name
ICN Pharmaceuticals and Schering Plough International provided free drug and placebo and financial support

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	29/08/2003		Yes	No