

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

Registration date

11/08/2003

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

05/09/2007

Condition category

Infections and Infestations

☐ Individual participant data

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

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

Rotterdam

Netherlands

3015 GD

Sponsor information

Organisation

Schering Plough International (USA)

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

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