

Short versus standard treatment with pegylated interferon alfa-2a plus ribavirin in patients with hepatitis C virus genotype 2 or 3: the CLEO trial

Submission date 15/01/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 22/01/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/12/2020	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Adriano M Pellicelli

Contact details
Via Terni 97 (private address)
Rome
Italy
00182

Additional identifiers

Protocol serial number
22/2006

Study information

Scientific Title
Short versus standard treatment with pegylated interferon alfa-2a plus ribavirin in patients with hepatitis C virus genotype 2 or 3: a randomised controlled trial

Acronym

Study short treatment (reduction duration)

Study objectives

To verify if a 12-week regimen of a combination of pegylated interferon alfa-2a and ribavirin was as efficacious as a 24-week regimen in patients with hepatitis C virus (HCV) genotype 2 or 3.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Committee of Azienda Ospedaliera San Camillo Forlanini approved in 2005 (ref: 489)

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic hepatitis C genotype 2 and 3

Interventions

Patients fulfilling the selection criteria received in an open-label fashion pegylated interferon alfa-2a at a dose of 180 µg subcutaneously once weekly and oral ribavirin, at a dosage of 1000 mg/day (for those with a weight of less than 75 kg) or 1200 mg/day (for those with a weight of greater than or equal to 75 kg). Patients with rapid virological response (RVR) defined as HCVRNA less than 50 IU/ml after 4 weeks of treatment, were randomly assigned in a 1:1 ratio to receive a treatment either for 12 weeks. Patients without RVR were treated for a standard period of 24 weeks.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Pegylated interferon alfa-2a, ribavirin

Primary outcome(s)

Sustained virological response (SVR) which was defined as undetectable plasma HCVRNA (less than 50 IU/ml) 24 weeks after the end of treatment.

Key secondary outcome(s)

1. Virological response rates (HCV RNA negative in serum with a detection limit of 50 IU/ml) at the end of therapy
2. Severity and frequency of adverse events

Completion date

10/01/2008

Eligibility

Key inclusion criteria

1. HCV ribonucleic acid (RNA) positive
2. HCV genotype 2 or 3
3. Elevated alanine aminotransferase (greater than 40 IU/L) at least 8 months prior to study entry
4. Histologically proven chronic HCV hepatitis
5. Naive to treatment
6. Aged 20 - 68 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

210

Key exclusion criteria

1. Known to have injected drugs or alcohol abuse (greater than 40 g ethanol/day) within the 6 months prior to study entry
2. Poorly controlled psychiatric illness
3. Decompensated cirrhosis
4. Positive for human immunodeficiency antibody virus or positive for hepatitis B surface antigen
5. Pregnancy, lactation
6. Impaired renal function
7. Other concurrent medical conditions of the liver different from HCV infection

Date of first enrolment

10/05/2006

Date of final enrolment

10/01/2008

Locations

Countries of recruitment

Italy

Study participating centre

Via Terni 97 (private address)

Rome

Italy

00182

Sponsor information

Organisation

Club Hepatology Hospital (Club Epatologi Ospedalieri [CLEO]) Group (Italy)

Funder(s)

Funder type

Research organisation

Funder Name

Club Hepatology Hospital (Club Epatologi Ospedalieri [CLEO]) Group (Italy)

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	19/02/2010	29/12/2020	Yes	No