Study to evaluate Pegasys® Sustained Viral Load (SVR) in genotype 3 Hepatitis C Virus (HCV) infected cirrhotic patients

Submission date Recruitment status Prospectively registered 03/12/2007 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 08/02/2008 Completed [] Results [] Individual participant data Last Edited Condition category [] Record updated in last year Infections and Infestations 16/10/2012

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

STEPS

Study objectives

The primary measure of efficacy will be Sustained Viral Load (SVR) defined as the percentage of patients with undetectable HC RNA (<50 IU/ml) in Group A (24 weeks of treatment) compared to Group B (48 weeks of treatment).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Main approval for Protocol Version 2.0 from Oxfordshire Research Ethics Committee (REC) C. Date of Approval: 22nd August 2007 (ref: 07/H0606/89)

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hepatitis C/ cirrhosis

Interventions

Group A: 180 mcg Pegasys® (subcutaneous) weekly and 800 mg Copegus® (oral) daily for 24 weeks

Group B: 180 mcg Pegasys® (subcutaneous) weekly and 800 mg Copegus® (oral) daily for 48 weeks

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Pegasys and Copegus

Primary outcome(s)

The primary measure of efficacy will be SVR defined as the percentage of patients with undetectable HC RNA (<50 IU/ml) in Group A compared to Group B.

All HCV RNA viral load measurements will be conducted with the Roche TaqMan HC test (See Secondary outcome measures for the timepoints of measurement).

Key secondary outcome(s))

- 1. SVR in Group A and B stratified by HCV viral load after 4 weeks of therapy (either <50 IU/ml or >= 50 IU/ml)
- 2. SVR in Group A and B stratified by HCV viral load after 12 weeks of therapy (either <50 IU/ml or >= 50 IU/ml)
- 3. Virological response at 4 weeks in Group A & B
- 4. Virological response at 12 weeks in Group A & B
- 5. Virological response at 24 weeks in Group A & B
- 6. Virological response at week 48 in Group B
- 7. Virological response in Group A + B by baseline parameters (Age, baseline fibrosis, baseline viral load)

All HCV RNA viral load measurements will be conducted with the Roche TagMan HC test.

Completion date

30/04/2009

Eligibility

Key inclusion criteria

- 1. Age >18 years of age
- 2. Chronic genotype 3 HCV infection as evidenced by HCV antibody and RNA positivity with genotype 3 infection confirmed at a central laboratory
- 3. Liver biopsy within 18 months of entry showing features of chronic HCV infection and modified Ishak fibrosis score of equal to or greater than 4 OR radiological and/or endoscopic features of cirrhosis
- 4. HBsAg negative
- 5. No clinical evidence of co-infection with HIV
- 6. Platelet count >70,000 cells/mm3, neutrophil count >600 cells/mm3
- 7. Compensated liver disease (Child-Pugh Grade A clinical classification)
- 8. Negative urine pregnancy test result (for females of childbearing potential) documented within the 24-hour period prior to the first dose of study drugs. Additionally, all female patients of childbearing potential and all males with female partners of childbearing potential must use two forms of effective contraception (combined) during treatment and 6 months after treatment end
- 9. Able and willing to give informed consent and able to comply with study requirements

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Key exclusion criteria

- 1. Previous therapy for chronic HCV infection: InterFeroN alpha (IFN), PEG-IFN, ribavirin, viramidine, levovirin, or investigational HCV protease or polymerase inhibitors
- 2. Patients who are expected to need systemic antiviral therapy with established or perceived activity against HCV at any time during their participation in the study
- 3. Evidence of other cause of significant liver disease: serum ferritin >1,000, biochemical evidence of Wilson's disease, autoantibody titres in excess of 1:160
- 4. Platelet count <= 70,000 cells/mm3, neutrophil count <= 600 cells/mm3
- 5. Poorly controlled diabetes that, in the opinion of the investigator, precludes therapy
- 6. Severe retinopathy that, in the opinion of the investigator, precludes therapy
- 7. Decompensated cirrhosis (Childs Pugh B or C)
- 8. The use of colony stimulating factors such as Granulocyte Solony Stimulating Factor (G-CSF), erythropoietin or other therapeutic agents to elevate haematology parameters to facilitate patient entry into the study
- 9. Haemoglobin concentration <12 g/dL in females or <13 g/dL in males or any patient with a baseline increased risk for anaemia (e.g., thalassemia, sickle cell anaemia, spherocytosis, history of gastrointestinal bleeding) or for whom anaemia would be medically problematic
- 10. Females who are pregnant or breast-feeding
- 11. History of severe psychiatric disease, including psychosis and/or depression, characterized by a suicide attempt, hospitalization for psychiatric disease, or a period of disability as a result of psychiatric disease
- 12. History of immunologically mediated disease (e.g., inflammatory bowel disease, idiopathic thrombocytopenic purpura, lupus erythematosus, autoimmune haemolytic anemia, scleroderma, severe psoriasis [defined as affecting >10% of the body, where the palm of one hand equals 1%, or if the hands and feet are affected], rheumatoid arthritis requiring more than intermittent nonsteroidal anti-inflammatory medications for management
- 13. History of severe cardiac disease (e.g., New York Heart Association [NYHA] Functional Class III or IV, myocardial infarction within 6 months, ventricular tachyarrhythmias requiring ongoing treatment, unstable angina or other significant cardiovascular diseases). In addition, patients with documented or presumed coronary artery disease or cerebrovascular disease should not be enrolled if, in the judgment of the investigator, an acute decrease in haemoglobin by up to 4 g /dL (as may be seen with ribavirin therapy) would not be well-tolerated
- 14. History of uncontrolled severe seizure disorder
- 15. Evidence of an active or suspected cancer or a history of malignancy within the last 2 years. Patients with a lesion suspicious for hepatic malignancy on an imaging study will be eligible only if the likelihood of carcinoma is <=10% following an appropriate evaluation
- 16. History of any systemic antineoplastic or immunomodulatory treatment (including supraphysiologic doses of steroids or radiation) <=6 months prior to the first dose of study drug or the expectation that such treatment will be needed at any time during the study
- 17. Other on-going serious medical condition in the opinion of the investigator that would prohibit treatment with Pegasys® or Copegus®
- 18. Poorly controlled thyroid dysfunction
- 19. History of major organ transplantation with an existing functional graft
- 20. Unable or willing to provide informed consent

Date of first enrolment

19/11/2007

Date of final enrolment

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Head of Research Resources London United Kingdom E1 2AN

Sponsor information

Organisation

Queen Mary University of London & Barts and the London NHS Trust (UK)

ROR

https://ror.org/026zzn846

Funder(s)

Funder type

Industry

Funder Name

Roche (Switzerland)

Alternative Name(s)

F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co., Roche Holdings, Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes