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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
Registration date	**Overall study status**	[_] Statistical analysis plan
08/02/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/10/2012	Infections and Infestations	[_] Record updated in last year

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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).

Secondary outcome measures
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 TaqMan HC test.

Overall study start date
19/11/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
140

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
30/04/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Head of Research Resources
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Sponsor information

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

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Sponsor type
Hospital/treatment centre

Website
http://www.bartsandthelondon.nhs.uk/research

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.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

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