

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr Gerry Leonard

### Contact details

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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  $\geq$  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  $\geq$  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/mm<sup>3</sup>, neutrophil count >600 cells/mm<sup>3</sup>
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  $\leq$  70,000 cells/mm<sup>3</sup>, neutrophil count  $\leq$  600 cells/mm<sup>3</sup>
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 Colony 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  $\leq 10\%$  following an appropriate evaluation

16. History of any systemic antineoplastic or immunomodulatory treatment (including supraphysiologic doses of steroids or radiation)  $\leq 6$  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**

London

United Kingdom

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## **Sponsor information**

#### **Organisation**

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

#### **Sponsor details**

Research and Development

Joint Research Office

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Whitechapel

London

England

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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