

# 40kD pegylated interferon alpha 2a plus ribavirin compared to 40 kD pegylated interferon alpha 2a plus ribavirin and mycophenolate in the management of patients with refractory chronic HCV infection

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 30/04/2018	<b>Condition category</b> Infections and Infestations	<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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0060110647

## **Study information**

### **Scientific Title**

40kD pegylated interferon alpha 2a plus ribavirin compared to 40 kD pegylated interferon alpha 2a plus ribavirin and mycophenolate in the management of patients with refractory chronic HCV infection

### **Study objectives**

In treating chronic HCV patients who failed to respond to standard interferon X, is the combination of PEG interferon plus ribavirin plus mycophenolate better than PEG plus ribavirin?

### **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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **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

### **Interventions**

Randomised, prospective trial.

### **Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Sustained response 24-28 weeks post completion of therapy

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/04/2002

**Completion date**

01/04/2004

## **Eligibility**

**Key inclusion criteria**

60 patients in each arm - 15-25 from Chelsea and Westminster NHS Trust

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

60

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/04/2002

**Date of final enrolment**

01/04/2004

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Chelsea and Westminster Hospital**  
London  
United Kingdom  
SW10 9NH

## **Sponsor information**

**Organisation**  
Department of Health

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

**Sponsor type**  
Government

**Website**  
<http://www.dh.gov.uk/Home/fs/en>

## **Funder(s)**

**Funder type**  
Hospital/treatment centre

**Funder Name**  
Chelsea and Westminster Healthcare NHS Trust (UK)

## **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