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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

Submission date	Recruitment status	[_] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2004	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/04/2018	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
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