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To investigate the role of folic acid in the management of ribavirin induced haemolytic anaemia in patients on combination treatment for chronic Hepatitis C virus infection

Submission date 30/09/2004	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Stopped	
Last Edited 16/09/2016	**Condition category** Infections and Infestations	

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
N0024131063

Study information

Scientific Title
To investigate the role of folic acid in the management of ribavirin induced haemolytic anaemia in patients on combination treatment for chronic Hepatitis C virus infection

Study objectives
The aim of this study is to assess if there are any beneficial effects of folic acid therapy in Ribavirin induced haemolytic anaemia.

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

Health condition(s) or problem(s) studied
Infections and Infestations: Hepatitis C

Interventions
Randomised controlled trial
1. Folic Acid
2. Placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Folic acid

Primary outcome measure
Rate of haemoglobin drop and rise and number of patients who have to have Ribavirin dose reduced due to anaemia

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2003

Completion date
30/08/2005

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
60 patients with chronic hepatitis C virus infection on combination therapy (30 will get folic acid and 30 placebo)

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/09/2003

Date of final enrolment
30/08/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Gastroenterology
London
United Kingdom
E9 6SR

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
Homerton University Hospital 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