

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	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 16/09/2016	Condition category 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

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Department of Gastroenterology

London

United Kingdom

E9 6SR

Sponsor information

Organisation

Department of Health

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Homerton University Hospital NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration