Adjunctive heparin in moderate to severe ulcerative colitis: a randomised multicentre controlled trial

Submission date	Recruitment status	☐ Prospectively registered
23/01/2004	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
23/01/2004	Stopped	☐ Results
Last Edited	Condition category	☐ Individual participant data
24/04/2009	Digestive System	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

Ulcerative colitis (US) is characterised by a relapsing and remitting course. The mainstay of therapy for relapses is steroids, with non-responders needing immunosuppressants or surgery. Recently heparin has been used with encouraging results but has not been subjected to a randomised controlled trial. There are sound theoretical reasons why heparin might work, and if this is so, will not only lead to improved treatment for this lifelong disease, but also to further avenues of investigation of the aetiology of inflammatory bowel disease. The objectives are to test whether heparin given in combination with corticosteroids to patients presenting with moderate to severe ulcerative colitis will increase the proportion of patients responding to treatment when compared with patients receiving corticosteroids alone. This inaugural study for the Group would launch the study group, and would further stimulate enthusiasm for research, forming the basis for future collaborations between researchers in the Northern and Yorkshire regions and with the Northern and Yorkshire Clinical Trials and Research Unit.

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

Inflammatory bowel disease

Interventions

Heparin with corticosteroids versus corticosteroids alone.

TRIAL HALTED DUE TO POOR RECRUITMENT.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Heparin, corticosteroids

Primary outcome measure

The trial aims to assess the time to clinical response, the time to relapse, the health related quality of life of patients and the safety of the two treatment regimens.

Secondary outcome measures

Not provided at time of registration

Overall study start date

06/01/1998

Completion date

04/01/2001

Reason abandoned (if study stopped)

TRIAL HALTED DUE TO POOR RECRUITMENT.

Eligibility

Key inclusion criteria

Patients presenting with moderate to severe ulcerative colitis

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

06/01/1998

Date of final enrolment

04/01/2001

Locations

Countries of recruitment

England

United Kingdom

Study participating centre North Tyneside Hospital Newcastle

United Kingdom NE29 8NH

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration