

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

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

B1034 R&D BARTON

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

North Tyneside Hospital

Newcastle

United Kingdom

NE29 8NH

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration