ISRCTN33332764 https://doi.org/10.1186/ISRCTN33332764

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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
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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 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