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Studies on the effects of rectal voltarol administration on the post-operative cytokine profile in serum and peritoneal fluid of patients undergoing major colorectal resection

Submission date 30/09/2004	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2004	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 30/08/2012	**Condition category** Surgery	[ ] 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
N0436130458

Study information

Scientific Title

Study objectives
To establish the effect of voltarol on the nature and levels of the cytokines present in the post-operative peritoneum and in serum. Any difference detected will be used to pursue further laboratory based research into the potential benefit of cyclo-oxygen

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
Surgery: Colorectal

Interventions
Not provided at time of registration

30/08/2012: Please note that this trial was stopped due to a lack of participants.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
voltarol

Primary outcome measure
Concentration of cytokines interleukin-IB (IL-IB) interleukin 6 (IL-6) and tumour necrosis factor-α (TNF-α) will be measured in the samples collected using the luminex platform. Prostaglandins E2 and F1 will also be measured.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2003

Completion date
01/11/2003

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Patients with a diagnosis of primary colorectal carcinoma undergoing elective laparotomy aged over 18.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

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
01/05/2003

Date of final enrolment

01/11/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Department of Surgery
Leeds
United Kingdom
LS9 7TF

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
Government

Funder Name
Leeds Teaching Hospitals 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