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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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2004	**Overall study status** Stopped	
Last Edited 30/08/2012	**Condition category** Surgery	

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
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration