

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/08/2012	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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-1B (IL-1B) 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