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Does peri-operative enteral nutrition and immunonutrition alter immunological response to surgery, improve blood supply to the gut and improve clinical outcome of patients undergoing restorative proctocolectomy?

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 12/09/2003	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 19/09/2016	**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

Protocol serial number
N0515088426

Study information

Scientific Title
Does peri-operative enteral nutrition and immunonutrition alter immunological response to surgery, improve blood supply to the gut and improve clinical outcome of patients undergoing restorative proctocolectomy?

Study objectives
Improved peri-operative enteral nutrition and immunonutrition beneficially alter the patient's immunological response to the insult of major pelvic surgery. Restorative proctocolectomy for ulcerative colitis is undertaken for two reasons, either because of the failure of medical management to control symptoms and dependence on immune suppressants or the risk of developing adenocarcinoma following many years of ulcerative colitis. Patients electing to undergo restorative proctocolectomy have therefore been suffering from a chronic disease that effects their nutritional and immune state, leading to higher rates of post operative complications including sepsis, leading to a significant increase in morbidity and hospital stay. Unfortunately, around 10% of ileoanal pouches fail and require excision the majority of these in the first 2 years due to pelvic sepsis. This trial will compare surrogate markers of immune modulation and clinical complications in fed and unfed groups to assess the benefit of peri-operative enteral nutrition.

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
Surgery: Restorative proctocolectomy

Interventions
Patients will be assigned to one of three groups:
Group 1 will receive normal pre-operative and post-operative care with no supplemental nutrition.
Group 2 will receive one week pre-operative supplemental enteral nutrition isocalorific and isonitrogenous to IMPACT to provide 25 Kcal/kg/day.
Group 3 will receive one week pre-operative supplemental enteral nutrition with IMPACT to provide 25 Kcal/kg/day.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Peripheral blood leukocyte subsets will be tested for intracellular pro-inflammatory cytokines InterLeukin-6 (IL-6), InterLeukin-2 (IL-2) and anti-inflammatory cytokine InterLeukin-10 (IL-10) using the technique of Carrock Sewell et al 1997. Phagocyte activity of both granulocytes and monocytes will be tested directly using fluroescein labeled opsonised bacteria. Blood will be taken prior to feeding, preoperatively, intraoperatively and on postoperative days three and seven. At laparotomy a biopsy of small bowel mucosa will be taken to assess leukocyte subsets for intracellular pro-inflammatory cytokines IL-6, IL-2 and anti-inflammatory cytokine IL-10. Phagocyte activity of both granulocytes will be tested directly using fluorescein labeled opsonised bacteria. Two further biopsies will be taken on days three and seven postoperatively for correlation with the peripheral blood immunology.

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

Completion date
31/03/2006

Eligibility

Key inclusion criteria
30 patients aged between 18-65 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/11/2000

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North West London Hospitals NHS Trust
Harrow, Middlesex
United Kingdom
HA1 3UJ

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
North West London Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration