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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 | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 12/09/2003 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 12/09/2003 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 19/09/2016 | Surgery | [ ] 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
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

### 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 measure
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.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/11/2000

### Completion date
31/03/2006

## Eligibility

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

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit

18 Years

**Upper age limit**
65 Years

**Sex**
Both

**Target number of participants**
30

**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**
England

United Kingdom

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

# Sponsor information

**Organisation**
Department of Health (UK)

**Sponsor details**
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

**Sponsor type**
Government

**Website**
http://www.doh.gov.uk

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
North West London 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