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# Intra-operative application of glycerine trinitrate (GTN) in anterior resection and pouch construction

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|---|---|---|
| **Submission date**<br>12/09/2003 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>12/09/2003 | **Overall study status**<br>Completed | |
| **Last Edited**<br>16/09/2014 | **Condition category**<br>Surgery | |

**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**
N0265109328

# Study information

### Scientific Title

### Study objectives
Not provided at time of registration

### 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: anterior resection and pouch construction

### Interventions
We should recruit 40 consenting patients in each group (AR and IPAA) to be randomly assigned to receive a single perioperative dose of topical 0.2% GTN (glycerine trinitrate) ointment or nothing. All patients to be assessed pre- and post-operatively with a clinical incontinence assessment, anorectal manometry and transanal ultrasound.

### Intervention Type
Drug

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Glycerine trinitrate

### Primary outcome measure

Not provided at time of registration

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

### Overall study start date
08/06/2002

### Completion date
08/06/2003

## Eligibility

### Key inclusion criteria
All patients submit to anterior resection (AR) and ileal pouch-anal anastomosis (IPAA)

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
80

### Key exclusion criteria
Not provided at time of registration

### Date of first enrolment
08/06/2002

### Date of final enrolment
08/06/2003

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre

**GI Surgery**
Birmingham
United Kingdom
B15 2TH

# 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**
Government

**Funder Name**
University Hospital Birmingham 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