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

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

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