

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

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/09/2014	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

Contact name
Dr MRB Keighley

Contact details
GI Surgery
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

GI Surgery

Birmingham

United Kingdom

B15 2TH

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

University Hospital Birmingham NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration