

Glyceryltrinitrate in the treatment of haemorrhoids

Submission date 23/01/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/11/2011	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr John Scholefield

Contact details
Department of Surgery
University of Nottingham
E Floor
West Block
Queen's Medical Centre
Nottingham
United Kingdom
NG7 2UH
+44 (0)115 970 9245
john.scholefield@nottingham.ac.uk

Additional identifiers

Protocol serial number
RBF 97XX8

Study information

Scientific Title

Study objectives

The proposed study will examine:

1. The physiology of anal canal mucosal blood flow and its relationship to pressures in the anal canal in patients with 1st and 2nd degree haemorrhoids compared to patients without disease
2. The effects of topical GTN formulations on anal canal pressure and its relationship to mucosal blood flow in the anal canal and in particular in 1st and 2nd degree haemorrhoids
3. The efficacy of treatment with GTN topical formulations compared to sclerotherapy or band ligation for 1st and 2nd degree haemorrhoids in a randomised trial
4. The delivery of topically applied GTN from novel formulations preparations and its optimisation

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

Haemorrhoids

Interventions

Not provided at time of registration

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Glyceryltrinitrate

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/08/1998

Eligibility

Key inclusion criteria

200 patients with 1st or 2nd degree haemorrhoidal disease attending the colorectal unit outpatient clinic.

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

01/09/1997

Date of final enrolment

31/08/1998

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Surgery

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

Funder(s)

Funder type

Government

Funder Name

NHS Executive Trent (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2003		Yes	No