

Glyceryltrinitrate in the treatment of haemorrhoids

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| Submission date 23/01/2004 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 23/01/2004 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 16/11/2011 | Condition category Digestive System | <input type="checkbox"/> Individual participant data |

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

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/1997

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

200

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

England

United Kingdom

Study participating centre
Department of Surgery
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive Trent (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

Study outputs

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