

Randomised study comparing the effects of lateral anal sphincterotomy, glyceryl trinitrate and botulinum toxin in the management of chronic anal fissures

Submission date 28/09/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 28/09/2007	Overall study status Completed	☐ Protocol
Last Edited 07/06/2017	Condition category Digestive System	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

N0051116137

Study information

Scientific Title

Randomised study comparing the effects of lateral anal sphincterotomy, glyceryl trinitrate and botulinum toxin in the management of chronic anal fissures

Study objectives

To determine whether botulinum toxin is clinically and financially an effective out patient alternative to Glyceryl Trinitrate and lateral anal sphincterotomy treatment of chronic anal fissures.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Double-blind randomised trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Digestive System: Chronic anal fissure

Interventions

Double-blind randomised trial, incorporating clinical and laboratory examinations prior to application of the drug at one week and one, two, three and six months post application.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Glyceryl trinitrate, botulinum toxin

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/03/2008

Eligibility

Key inclusion criteria

120 males and females aged 18-65

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/04/2002

Date of final enrolment

31/03/2008

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Brighton & Sussex University Hospitals NHS Trust (RSCH)

Brighton

United Kingdom

BN2 5BE

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Brighton and Sussex University Hospitals NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration