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

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/09/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/06/2017	**Condition category** Digestive System	[_] 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 botulinium toxin in the management of chronic anal fissures

Study objectives
To determine whether botulinium 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

Study design
Double-blind randomised trial

Primary study design
Interventional

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, botulinium 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