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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2002

Completion date
31/03/2008

Eligibility

Key inclusion criteria
120 males and females aged 18-65

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
120

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
England

United Kingdom

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

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.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Brighton and Sussex University Hospitals NHS Trust (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