

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr Paul Farrands

### Contact details

Brighton & Sussex University Hospitals NHS Trust (RSCH)

Royal Sussex County Hospital

Eastern Road

Brighton

United Kingdom

BN2 5BE

+44 (0)1273 696955 X 4647

paul.farrands@bsuh.nhs.uk

## 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

**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, 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes