

# A randomised controlled trial to evaluate topical 10% metronidazole ointment for the treatment of perianal Crohn's disease

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/11/2011	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N0013150230

# Study information

## Scientific Title

### Study objectives

Does topical metronidazole treat patients with peri-anal Crohn's disease?

### 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

Crohn's disease

### Interventions

This is a randomised, double blind, placebo-controlled, parallel group clinical trial comparing placebo and 10% metronidazole ointment for the treatment of perianal Crohn's disease.

### Intervention Type

Drug

### Phase

Not Applicable

### Drug/device/biological/vaccine name(s)

10% metronidazole ointment

**Primary outcome measure**

Peri-anal Crohn's disease activity index.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/06/2004

**Completion date**

01/12/2004

## Eligibility

**Key inclusion criteria**

30 patients with peri-anal Crohn's disease will be recruited throughout the course of the trial.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

30

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/06/2004

**Date of final enrolment**

01/12/2004

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

General, Vascular & Colorectal Surgery  
London

United Kingdom  
SE1 7EH

## Sponsor information

### Organisation

Department of Health

### Sponsor details

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

Government

### Funder Name

Guy's and St. Thomas' NHS Foundation Trust (UK)

### Funder Name

Own account

### Funder Name

NHS R&D Support Funding (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?
<a href="#">Results article</a>	results	01/09/2010		Yes	No