

# 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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## Additional identifiers

### Protocol serial number

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

### Study type(s)

Treatment

### 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(s)

Peri-anal Crohn's disease activity index.

### Key secondary outcome(s))

Not provided at time of registration

### 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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**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**

United Kingdom

England

**Study participating centre**

General, Vascular & Colorectal Surgery

London

United Kingdom

SE1 7EH

**Sponsor information****Organisation**

Department of Health

**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

### 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