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

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 14/11/2011	**Condition category** Digestive System	

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
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
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+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?
Results article	results	01/09/2010		Yes	No