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Randomised trial comparing needle drainage of perianal abscess under local anaesthetic to conventional treatment by incision and drainage under general anaesthetic

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 19/08/2015	**Condition category** Signs and Symptoms	[_] 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

N0594142233

Study information

Scientific Title
Randomised trial comparing needle drainage of perianal abscess under local anaesthetic to conventional treatment by incision and drainage under general anaesthetic

Study objectives
Can perianal sepsis be treated on an outpatient basis by needle drainage and antibiotics?

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)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Signs and Symptoms: Perianal sepsis

Interventions
Needle drainage or incision and drainage under general anaesthesia.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Failure of aspiration: the number of patients in this group requiring I&D subsequent to aspirations

2. Number of aspirations required
Number of patients requiring EUA for fistula
Patient acceptability

Secondary outcome measures
Not provided at time of registration

Overall study start date
24/02/2004

Completion date
31/05/2006

Eligibility

Key inclusion criteria
Patients with fluctuant perianal sepsis are recruited on presentation to Accident and Emergency

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Ongoing until 100 patients are accrued - 30 patients have currently been recruited as of August 2005.

Key exclusion criteria
1. Diabetic patients
2. Patients under 16
3. Pregnant patients
4. Patients who are immunosuppressed
5. Patients with an obvious perianal fistula
6. Patients in whom other pathology is suspected (e.g. anal cancer)

Date of first enrolment
24/02/2004

Date of final enrolment
31/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Luton & Dunstable Hospital NHS Trust
Luton
United Kingdom
LU4 0DZ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
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dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Luton and Dunstable 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