

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/08/2015	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English Summary

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

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 hypothesis

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

Condition

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

Overall study end date

31/05/2006

Eligibility

Participant 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.

Participant 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)

Recruitment start date

24/02/2004

Recruitment end date

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