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Single centre randomised study to discover whether fibrin glue is more effective than surgery in the treatment of pilonidal sinus

Submission date	Recruitment status	[_] Prospectively registered
29/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/03/2012	Skin and Connective Tissue Diseases	

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
N0077161769

Study information

Scientific Title

Study objectives
To determine the effectiveness of fibrin glue in the treatment of pilonidal sinus, as compared to standard surgical techniques.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added September 2008: Nottingham One Ethics Research Committee (UK).

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

Health condition(s) or problem(s) studied
Skin and Connective Tissue Diseases: Pilonidal sinus

Interventions
Randomised Controlled Trial. Patients that present with pilondial sinus at outpatient clinic will be invited to participate in the study. Forty patients will be recruited. Having given informed consent, patients will be randomised into two groups and the second group will be the control group. The treatment group will be prepared for surgery as routine. Under a general anaesthetic the openings of the sinus. The pits will then be injected with fibrin glue (Tisseel, Baxter Healthcare Ltd, Newbury, UK). One to be mls of glue will be injected. A simple non-woven dressing will be applied. No antibiotic prophylaxis will be given. Patients will be discharged from hospital after the procedure. Six months after the procedure patients will be contacted by telephone and complications or recurrences will be recorded. They will be given a linear

analogue pain score to complete daily for the week following their procedure. This will record the patients pain and also the time taken to return back to normal activities. The patients in the control group will be managed as above, but instead of being treated with fibrin glue they will receive standard surgery.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Reduction in Pain
2. Healing rate.

Secondary outcome measures
Added September 2008:
Recurrence, infection, return to work and cost.

Overall study start date
30/03/2005

Completion date
31/12/2008

Eligibility

Key inclusion criteria
Patients with pilonidal sinus under the care of Consultant Surgeons within the Derby NHS Foundation Trust will be identified from GP referral letters to surgical outpatients. Patients will be approached on visiting outpatients. Patients will be given both verbal and written information to enable them to make an informed decision as to whether to proceed. Patients have the right to withdraw at any stage.

Inclusion criteria:
1. Male and Female subjects with pilonidal sinus
2. Patients > 18 years old
3. Only women taking adequate contraceptive precautions
4. Patients with no history of allergy to any of the product contents of Tisseel Kit sealant.
5. Ability to provide valid informed consent.
6. Patients who have no objections on moral/religious grounds to the product (Tisseel contains human fibrin and Aprotinin from cattle)

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Women who are lactating
2. Women who are pregnant
3. Women of childbearing age who are unwilling to take adequate contraceptive precautions
4. Patients with allergic diathesis or patients who have had previous exposure to aprotinin

Date of first enrolment
30/03/2005

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Derby Hospitals NHS Foundation Trust
Derby
United Kingdom
DE22 3DT

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, 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
Derby Hospitals NHS Foundation Trust (UK), NHS R&D Support Funding

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	pilot study results	01/05/2005		Yes	No