

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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 Deptember 2008: Nottingham One Ethics Research Committee (UK).

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Skin and Connective Tissue Diseases: Pilonidal sinus

Interventions

Randomised Controlled Trial. Patients that present with pilonidal 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(s)

1. Reduction in Pain
2. Healing rate.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

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

Funder(s)

Funder type

Government

Funder Name

Derby Hospitals NHS Foundation Trust (UK), NHS R&D Support Funding

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?
Results article	pilot study results	01/05/2005		Yes	No