

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

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| <b>Submission date</b><br>29/09/2006   | <b>Recruitment status</b><br>No longer recruiting                | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>29/09/2006 | <b>Overall study status</b><br>Completed                         | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>28/03/2012       | <b>Condition category</b><br>Skin and Connective Tissue Diseases | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input checked="" type="checkbox"/> Results          |
|  |  | <input type="checkbox"/> 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).

### Study design

Randomised controlled trial

### Primary study design

Interventional

### 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 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(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? |
|---------------------------------|---------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | pilot study results | 01/05/2005   |            | Yes            | No              |