# Pit Excision with Phenolisation of the Sinus Tract vs. Radical Excision in Sacrococcygeal Pilonidal Sinus Disease; A Randomised Controlled Trial

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The objective of this study is to show that excision of the pit of the sinus of SPSD with phenolisation of the sinus tract is accompanied with sooner return to normal daily activities compared to local excision of the sinus with only a small...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Skin and subcutaneous tissue disorders NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON41550

**Source**
ToetsingOnline

**Brief title**
Phenolisation vs. Radical Excision in Pilonidal Sinus Disease

### Condition

- Skin and subcutaneous tissue disorders NEC

**Synonym**
nest of hairs, Pilonidal sinus disease

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Diakonessenhuis Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Phenolisation, Randomised controlled trial, Sacrococcygeal Pilonidal Sinus Disease, Surgery

## Outcome measures

### Primary outcome

Loss of days of normal activities/ working days.

### Secondary outcome

Anatomic recurrence rate, symptomatic recurrence rate, quality of life,

surgical site infection, time-to-wound-closure, symptoms related to treatment,

pain, usage of pain medication, total treatment time.

# Study description

### Background summary

Sacrococcygeal pilonidal sinus disease (SPSD) is an acquired disorder of the natal cleft. Excision of the pit of the sinus with phenolisation of the sinus tract and surgical excision are two frequently used treatment modalities for SPSD. Phenolisation seems to have advantages over local sinus excision as it is performed under local anaesthesia with a relatively small surgical procedure, less postoperative pain, minor risk of surgical site infection (8.7%) and only a few days unable to do normal activity (mean of 2.3 days). The disadvantage may be that phenolisation may be repeated a second time and the higher risk of recurrence (13%). Surgical excision of SPSD has a recurrence rate of 11%. The disadvantages, however, are the postoperative pain and the high risk of surgical site infection and the hereby large amount of days with loss of normal activities (mean of about 10 days). So, the recurrence risk based on the current non-randomised studies is some higher for the phenolisation treatment but the number of days unable to do normal activities is highly favourable, probably due to less pain and less risk of surgical site infections.

### Study objective

The objective of this study is to show that excision of the pit of the sinus of

SPSD with phenolisation of the sinus tract is accompanied with sooner return to normal daily activities compared to local excision of the sinus with only a small increase of recurrence rate.

### Study design

Randomised controlled trial.

### Intervention

Excision of the pit of the sinus followed by phenol applications of the sinus tract compared to radical surgical excision of the sinus.

### Study burden and risks

The risks are low for both treatment modalities as the safety of both has already been established. Excision of the pit of the sinus with phenolisation of the sinus tract seems to have advantages as it is performed under local anaesthesia, gives less postoperative pain, low risk of surgical site infection and only a few days unable to do normal activities. The disadvantage may be the some higher risk of recurrence. However, it seems unlikely that this treatment does compromise or negatively influence surgical excision if necessary in the future. Surgical excision of SPSD is currently the most frequently used treatment for symptomatic chronic SPSD. The disadvantage of this treatment are the postoperative pain, high risk of surgical site infection and the large amount of days with loss of normal activities. The burden of this study is low for the participating patients as we only ask the patients to answer some questions by a questionnaire preoperatively and at some points after the operation. The number and time of out-clinic visits are not different compared to the normal treatment of SPSD.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

1) Patient with symptoms due to chronic SPSD interfering with life
2) Age >= 18 years
3) Written informed consent is obtained

## Exclusion criteria

1) No or minimal symptoms related to SPSD
2) Suspicion of extensive subcutaneous network of sinus tracts, especially in the case of more than three off-midline orifice, as these sinuses are not eligible for phenolisation treatment
3) Abscess of SPSD
4) Previous surgical procedures for SPSD

# Study design

## Design

**Study type:** Interventional

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |

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| Primary purpose: | Treatment |

### Recruitment

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 20-09-2013 |
| Enrollment: | 100 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 18-06-2013 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 28-12-2015 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
| --- | --- |
| CCMO | NL43192.100.13 |