Sinus pilonidalis (haarnestcyste in de bilspleet): fenolisatie (dichtbranden) vs. radical excisie (operatieve behandeling); een gerandomiseerde studie

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29335

Source
NTR

Brief title
N/A

Health condition

Sacrococcygeal Pilonidal Sinus Disease
Haarnestcyste
Sinus pilonidalis

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Loss of days of normal activities/ working days (measured from the start of the treatment).

Secondary outcome

1) Anatomic recurrence rate;

2) Symptomatic recurrence rate (Visick satisfaction rate);

3) Quality of Life (obtained by the Short Form-36 (SF-36) and visual analogue scale);

4) Surgical site infection (cellulitis vs. abscess, treatment must be necessary to report a surgical site infection, i.e. antibiotics or opening of the wound) scored by the Southampton wound scoring system;

5) Time-to-wound-closure (complete epithelisation);

6) Symptoms related to treatment (fluid, pain, irritation, itch, burning);

7) Pain (daily scored by a visual analogue scale during the first two weeks after each operation; daily mean score after treatment and total days of pain determined);

8) Usage of pain medication;

9) Total treatment time (from start of treatment to cure of the Sacrococcygeal Pilonidal Sinus Disease);

10) Sexual function (Sexual Self-Consciousness Scale, SSCS).

Study description

Background summary

Background/ rationale:

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 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 has to be repeated a second time in some patients and the some 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.

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 in recurrence rate.

Study design:

Randomised controlled trial.

Study population:

All patients who present in the out-patient clinic of the participating centre in the Netherlands with SPSD.

Intervention:

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

Primary endpoint: loss of days of normal activities/ working days.

Study objective

The hypothesis of this study is that phenolisation of the sinus tract vs. primary surgical excision in patients with a symptomatic sacrococcygeal pilonidal sinus disease reduces days unable to do normal activities with only a small increase in recurrence rate.

Study design

1) diary for the first two weeks after surgical excision or after each phenolisation procedure;

2) postoperative questionnaire for patients (obtained after 2, 6, 12, 26 and 52 weeks);

3) postoperative assessment form for the physician (obtained after 1-6, 12, 26 and 52 weeks).

Intervention

Intervention: Pit excision of the sacrococcygeal pilonidal sinus disease, debridement of the sinus tract followed by phenolisation of the sinus tract under local anesthesia in an ambulatory setting.

Comparison: Radical surgical excision of the sinus tract and primary closure of the wound under spinal or general anesthesia in an one-day surgery setting.

Contacts

Public
AIOS Chirurgie
Diakonessenhuis Utrecht
Bosboomstraat 1
Postbus 80250

E.J.B. Furnée
Utrecht 3508 TG
The Netherlands
088 – 250 6615
Scientific
AIOS Chirurgie
Diakonessenhuis Utrecht
Bosboomstraat 1
Postbus 80250

E.J.B. Furnée
Utrecht 3508 TG
The Netherlands
088 – 250 6615

Eligibility criteria

Inclusion criteria

1) Patient with symptoms due to chronic Sacrococcygeal Pilonidal Sinus Disease interfering with life (non-silent Sacrococcygeal Pilonidal Sinus Disease);

2) Age ≥ 18 years;

3) Written informed consent is obtained.

Exclusion criteria

1) No or minimal symptoms related to Sacrococcygeal Pilonidal Sinus Disease;

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 Sacrococcygeal Pilonidal Sinus Disease;

4) Previous surgical procedures for Sacrococcygeal Pilonidal Sinus Disease.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2013
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	24-06-2013
Application type:	First submission

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
NTR-new	NL3882
NTR-old	NTR4043
Other	METC: Verenigde Commissies Mensgebonden Onderzoek (VCMO) : ABR-43192
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A