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

Gepubliceerd: 24-06-2013 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29335

Bron
NTR

Verkorte titel
N/A

Aandoening

Sacrococcygeal Pilonidal Sinus Disease
Haarnestcyste
Sinus pilonidalis

Ondersteuning

Primaire sponsor: N/A
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2013
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	24-06-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A