Comparing Minimally Invasive Treatments for Pilonidal Disease: LA POPA trial (Laser And Pit-picking OR Pit-picking Alone)

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The main objective of this study is to establish the efficacy of *pit picking with laser therapy* versus *pit picking alone* on both short and long-term outcomes.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anal and rectal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON56718

Source
ToetsingOnline

Brief title
LA POPA

Condition

- Anal and rectal conditions NEC

Synonym
pilonidal cyst, Pilonidal sinus disease

Research involving
Human

Sponsors and support

Primary sponsor: Albert Schweitzer Ziekenhuis
Source(s) of monetary or material Support: subsidie van wetenschapsafdeling van het

Albert Schweitzer ziekenhuis (=sponsor/verrichter)

Intervention

Keyword: Laser assisted therapy, Minimally invasive treatment, Pilonidal sinus disease, Pit-picking

Outcome measures

Primary outcome

Primary endpoint: The overall success rate of treatment which is defined as:

closure of all pits, and the absence of symptoms, persisting sinuses or

recurrence of pilonidal disease within 12 months.

Secondary outcome

Secondary endpoints: wound closure time, patient experience, pain,

complications, work rehabilitation, time to return to daily activities, quality

of life, costs and the need for secondary or revision surgery.

Time points of measurement are defined as: T = 0 (baseline), 2 weeks, 4 weeks,

6 weeks, 6 months, 1, 3 and 5 year after treatment.

Study description

Background summary

Pilonidal sinus disease (PSD) is a burdening disease with a prevalence of 26/100.000 individuals, mostly affecting young men. Conventional treatment of pilonidal disease consists of a wide array of excisional surgery techniques, often requiring multiple operations, which lead to high morbidity and significant medical costs. Pit picking is a simple minimally invasive approach that can be performed in an outpatient clinic setting with local anaesthesia, potentially lower costs and higher overall patient satisfaction. However, higher recurrence rates have been reported. Adjuvant laser therapy might provide a valuable option to decrease recurrence rates and improve wound healing time, but the benefit of the laser has to be established yet.

Study objective

The main objective of this study is to establish the efficacy of *pit picking with laser therapy* versus *pit picking alone* on both short and long-term outcomes.

Study design

The study concerns a multicentre, single-blinded, randomised, controlled, superiority trial. It will investigate the additional value of laser therapy regarding the success rate of treatment. Patients will be accrued by all participating centres. The design involves allocation of all appropriate consecutive patients with primary pilonidal sinus disease to pit picking alone or combined with laser therapy. Data will be analysed on *intention to treat* and *treated as* basis.

Intervention

Pit picking surgery alone or combined with laser therapy. Both interventions are considered standard of care in the participating centres.

Study burden and risks

The extra burden for participating patients is expected to be minimal to moderate. Patients will have two extra hospital visits in case they are enrolled in our study: 6 and 12 months after enrolment. Postoperatively the normal scheme of follow up appointments will be used: 2 and 6 weeks after treatment at the outpatient clinic of the treating surgeon. A telephone appointment with the researcher will be scheduled 4 weeks after treatment. Patients are asked to complete questionnaires at various time points, which will be sent to them by email and will take approximately 5-10 minutes each time. The content includes general and disease specific Quality of Life (QoL) questionnaires. We do not expect any extra adverse reactions or events in respect to participation in the study because both procedures are considered standard of care in the participating clinics. However, because both interventions are surgical procedures a small percentage of adverse events or postoperative complications can be expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• All patients aged 12 years and older who present with primary pilonidal sinus disease; Type 1b and 3 of the Dutch staging system
• Obtained written informed consent by the patient and/or legal representative/parent
• Sufficient understanding of the Dutch written language (reading and writing)
• Eligible for questionnaires sent by e-mail

Exclusion criteria

• Asymptomatic (Type 1a), recurrent (Type 4; except those patients who only have had drainage of their abscess and no other surgical treatment), or chronic wounds (hypergranulating) after PSD surgery (Type 5) of the Dutch staging system.
• Patients with known underlying or concomitant medical conditions that may interfere with normal wound healing (e.g. systemic skin and connective tissue diseases, any kind of congenital defect of metabolism including

insulin-dependent diabetes mellitus, Cushing syndrome or disease, scurvy, chronic hypothyroidism, congenital or acquired immunosuppressive condition, chronic renal failure, or chronic hepatic dysfunction (Child-Pugh class B or C), severe malnutrition, or other concomitant illness which, in the opinion of the investigator, has the potential to significantly delay wound healing)
• Severe drug abuse (and therefore protocol deviation can be expected)
• Patients expected not to comply with the study protocol (including patients with severe cognitive dysfunction/impairment and severe psychiatric disorders)
• Patients with insufficient knowledge of the Dutch written language who are thus unable to answer the questionnaires
• Patients that are unable or not willing to give full informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2024
Enrollment:	431
Type:	Actual

Ethics review

Approved WMO Date:	26-03-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-10-2024

Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT06140199
CCMO	NL84679.018.23