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A study comparing a hemp-herbal topical ointment with topical nifedipine-lidocaine in patients with chronic anal fissure

Submission date
16/04/2026

Recruitment status
No longer recruiting

Registration date
23/07/2026

Overall study status
Completed

Last Edited
23/07/2026

Condition category
Digestive System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific, Principal investigator, Public

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Additional identifiers

Study information

Scientific Title
Efficacy and safety of a hemp-herbal topical ointment versus nifedipine-lidocaine for the treatment of chronic anal fissure: a double-blind randomized controlled trial

Study objectives
To evaluate the efficacy and safety of a hemp-herbal topical ointment compared with topical nifedipine-lidocaine in the treatment of chronic anal fissure, with respect to symptom relief, healing rates, and adverse events.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/12/2022, Institutional Helsinki Committee, Sheba Medical Center (Emek Ha hela, Ramat Gan, 526501, Israel; +972-03-5308916, 972-052-3491626; Helsinki@sheba.health.gov.il), ref: SMC0128-23

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Chronic anal fissure

Interventions
Participants are allocated in a 1:1 ratio using a pharmacy-generated blocked randomisation sequence with blocks of 10 (five allocations to each treatment within every block). The dispensing pharmacy prepares identical coded study tubes according to the randomisation schedule. Participants, investigators, treating clinicians and outcome assessors remain blinded throughout the study. The pharmacy retains the allocation code and emergency unblinding is permitted only when clinically required.

Participants were randomly assigned to receive either a hemp-herbal topical ointment or a topical nifedipine (0.3%) plus lidocaine (2%) ointment. Both treatments were applied locally to the anal canal twice daily for a period of 8 weeks.
Study medications were prepared in identical containers to maintain blinding. Patients were instructed on a standardized application technique and were followed at predefined intervals for clinical assessment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Proctofiz MD Ointment, topical nifedipine-lidocaine

Primary outcome(s)
1. Complete fissure healing measured using data on clinical healing, defined as complete epithelialization of the fissure on anorectal examination, without associated pain during defecation at 6 weeks after treatment initiation

2. Pain reduction measured using a Visual Analog Scale (VAS) score at baseline and 6 weeks

Key secondary outcome(s)

Completion date
15/11/2025

Eligibility

Key inclusion criteria
1. Adults aged ≥18 years with clinically confirmed chronic anal fissure
2. Chronic anal fissure defined as a symptomatic fissure persisting for ≥6 weeks, with typical features on anorectal examination (e.g., sentinel tag, indurated edges, or exposed internal sphincter fibers)
3. Presence of fissure-related pain during or after defecation
4. Ability to provide informed consent
5. A threshold of 3 weeks was used to reflect institutional clinical practice and to include patients with persistent fissures refractory to conservative therapy

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Acute anal fissure (<3 weeks duration)
2. Anal fissure associated with inflammatory bowel disease (e.g., Crohn’s disease)
3. Previous anorectal surgery affecting the anal canal
4. Use of topical treatments for anal fissure within 2 weeks prior to enrollment
5. Known hypersensitivity to nifedipine, lidocaine, or components of the study ointment
6. Pregnancy or breastfeeding
7. Severe comorbid conditions that could interfere with study participation or outcome assessment

Date of first enrolment
01/02/2023

Date of final enrolment
22/09/2025

Locations

Countries of recruitment
Israel

Study participating centre
Sheba Medical Center
-
-
Israel
-

Sponsor information

Organisation
Sheba Medical Center

ROR
https://ror.org/020rzx487

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1		23/07/2026	No	Yes
Participant information sheet	Patient instructions for ointment application version 1.0		23/07/2026	No	Yes
Protocol file	version 1.0	22/07/2026	23/07/2026	No	No