Official Title:
Tumescent Local Anesthesia versus Conventional Local Anesthesia for Sinus Laser Closure (SiLaC)

NCT Number:
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Document:
Study Protocol

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Institution:
Opća Županijska Bolnica Požega - General County Hospital Požega

Principal Investigator:
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Study Type:
Prospective, randomized, single-center interventional study

Study Period:
01 September 2025 – 31 August 2027

Study Protocol

Background:

Pilonidal disease affects approximately 2% of the population and significantly reduces quality of life. Local anesthesia has been shown to reduce postoperative pain and hospital stay. Tumescent local anesthesia may further improve outcomes, but evidence in laser treatment of pilonidal sinus is lacking.

Objective:

To compare postoperative pain between conventional and tumescent local anesthesia in laser treatment of pilonidal sinus.

Hypothesis:

There is a statistically significant difference ($p < 0.05$) in VAS pain scores between the two anesthesia techniques.

Methods:

Approximately 100 adult patients undergoing laser treatment for pilonidal sinus will be enrolled. Participants will be randomized using sealed envelopes. Pain will be assessed using the VAS scale preoperatively and on postoperative days 1, 2, and 7.

Inclusion Criteria:
- Adults ≥18 years
- Diagnosed pilonidal sinus disease
- Laser treatment for pilonidal sinus disease - Able to provide informed consent

Exclusion Criteria:
- Minors
- Recurrent pilonidal sinus - Chronic pain syndrome
- Prisoners

Ethics:

Participation is voluntary. Written informed consent will be obtained. Data will be collected anonymously.

Expected Outcome:

Identification of an anesthesia technique associated with less postoperative pain and improved patient satisfaction.