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Prospective Cohort Study on Surgical Methods and Outcomes in Emergency Groin and Ventral Hernia Repairs in Finland

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Study Group

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1. Introduction and Background

Hernia surgery is among the most common surgical procedures with the majority performed as elective operations. However, the proportion of emergency procedures is considerable, and these are associated with significantly higher morbidity and mortality compared with elective surgery.

In Finland, approximately 500 emergency groin hernia repairs and 600 ventral hernia repairs are performed annually. Current treatment practices for emergency hernia surgery vary substantially, and

scientific evidence on management and outcomes is lacking. Existing guidelines are partly outdated and largely based on expert opinion.

The aim of this study is to provide new, scientifically robust evidence on the outcomes, complications, and postoperative quality of life following emergency hernia surgery.

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2. Study Objectives

The primary objective is to assess the short- and long-term outcomes of different surgical techniques in emergency groin and ventral hernia repairs. Specifically, the study will evaluate:

- Surgical outcomes and complications within 30 and 90 days postoperatively
- Risk of recurrence and quality of life at 1, 2, and 5 years
- Impact of wound and mesh infections, as well as other postoperative factors, on recurrence
- Effectiveness and safety of different surgical techniques

The results will support more evidence-based and precise recommendations on surgical methods, urgency classification, and the role of surgeon expertise.

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3. Study Design and Patient Cohort

This is a multicenter study with a prospective patient cohort of emergency groin and ventral hernia repairs. Patients will be recruited over two years and followed up for five years postoperatively. The aim is to include as many eligible patients as possible.

Inclusion criterion

- Emergency repair of a groin or ventral hernia

Exclusion criteria

- Pregnancy
- Age under 18 years
- Advanced malignancy
- Inability to follow up (e.g., long travel distance or poor functional status)
- Participation in another study
- Lack of informed consent

Estimated sample size: ~600 patients recruited across participating Finnish hospitals.

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4. Methods and Data Collection

Data will be collected in the REDCap system at the following time points:

1. **Baseline (preoperative):** Patient demographics (age, sex, BMI) and comorbidities
2. **Intraoperative:** Surgical technique, procedures performed, duration of surgery
3. **Postoperative (hospital stay):** Recovery, complications, reoperations
4. **Follow-up at 30 days, 90 days, 1, 2, and 5 years:**
    - Recurrence (clinically and with imaging if needed)
    - Quality of life (RAND-36, AAS, PROMIS)
    - Complications, readmissions, recovery time, sick leave

Patients will be contacted by phone at each follow-up. If recovery is delayed, complications are suspected, or recurrence is possible, patients will be invited for further assessment at the hospital where the surgery was performed.

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5. Statistical Analysis

The **primary endpoint** is hernia recurrence within two years after surgery.

Statistical methods include:

- Kaplan-Meier analysis for comparison of surgical techniques
- Chi-square test and Fisher's exact test for categorical variables
- Student's t-test for continuous variables
- Multivariate analysis for independent risk factors

Analyses will be conducted using IBM SPSS Statistics. A p-value < 0.05 will be considered statistically significant.

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6. Ethical Considerations and Data Protection

The study has been approved by the Ethics Committee of the Wellbeing Services County of North Ostrobothnia. Local research permits will be obtained from each participating hospital before study initiation.

Participation is voluntary, and written informed consent will be obtained from all patients. Clinical management will follow local treatment protocols regardless of study participation. Patient data will be stored in a pseudonymized form. The data controller is the Wellbeing Services County of North Ostrobothnia.

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7. Timeline

- **2024–2026:** Patient recruitment and initiation of follow-up. Study start date: October 1st 2025 across all participating hospitals.
- **2028:** Data analysis and first publication on the primary endpoint
- **2031:** Completion of follow-up and publication of long-term outcomes

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8. Funding Plan

Estimated Costs

- Research nurse contribution (8h/week): €11,200 per year

The study will not incur additional costs to participating hospital districts. Research nurse resources are required for patient follow-up.