

STUDY PROTOCOL

Study name:	Effectiveness of enhanced recovery after surgery (ERAS) protocols for arthroscopic anterior cruciate ligament reconstruction in an ambulatory surgery setting
Duration:	April 16 th 2026 - April 16 th 2027

1. Study Description (Brief summary)

The anterior cruciate ligament (ACL) is a critical component for maintaining knee stability by resisting anterior tibial translation and internal rotation. ACL rupture is one of the most common orthopedic injuries, with an estimated incidence of 70 cases per 100,000 people annually [1]. Since its inception, arthroscopic anterior cruciate ligament reconstruction (AACLRL) has proven to be the gold standard, providing excellent outcomes in terms of graft longevity, return to sports, and patient satisfaction [2]. Modern medical trends are shifting toward day-surgery protocols, where patients are discharged within 24 hours without an overnight stay. This model is identified as a major factor in enhancing the quality of postoperative recovery and patient satisfaction [3].

The Enhanced Recovery After Surgery (ERAS) program utilizes evidence-based multimodal interventions to reduce surgical stress and accelerate functional recovery. While day-surgery for AACLRL has been proven feasible globally, its implementation in Vietnam remains limited due to systemic barriers [4,5]. At the University Medical Center Ho Chi Minh City, although ERAS has been applied since 2022, the average length of stay for AACLRL is 2.57 days, indicating significant room for optimization. This study aims to evaluate the current compliance with ERAS and the effectiveness of fully implementing these protocols to enable a day-surgery model.

The research is designed in two phases, including a descriptive cohort and a clinical intervention. The intervention focuses on 06 core ERAS measures:

- Comprehensive preoperative counseling and education.
- Reducing preoperative fasting by using Maltodextrin 2 hours before surgery.
- Standardized anesthesia combined with local infiltration analgesia (LIA).
- Multimodal analgesia to minimize opioid consumption.
- Early drainage removal within 6–8 hours postoperatively.
- Immediate postoperative rehabilitation starting in the recovery unit.

Effectiveness will be measured through various outcomes: the quality of early recovery via the QoR-15 score, mechanical knee function via the Lysholm Knee Scoring Scale (LKSS), and health-related quality of life via the EQ-5D-5L. Furthermore, a cost-effectiveness analysis (CEA) will be conducted using the Incremental Cost-Effectiveness Ratio (ICER). The study expects to demonstrate that strict ERAS adherence makes day-surgery ACLR feasible, reduces hospital-acquired infections, optimizes operating room productivity, and lessens the financial burden on both patients and the healthcare system.

2. Objective

- 2.1. To describe the current status of ERAS program implementation among patients undergoing arthroscopic anterior cruciate ligament reconstruction (ACLR) at University Medical Center Ho Chi Minh City.
- 2.2. To evaluate the impact of ERAS interventions on postoperative recovery quality, cost-effectiveness, and the feasibility of implementing a day-surgery protocol for patients undergoing ACLR.

3. Materials and methods

Study design: Two-phase study

- Phase 1: Cross-sectional study, Retrospective cohort study.
- Phase 2: Interventional study.

Observational Model: Cohort

Actual study start date: April 16th, 2026

Actual study completion date: April 16th, 2027

4. Criteria

Inclusion criteria

- Patients aged 18 years and older.
- Diagnosis of anterior cruciate ligament (ACL) rupture with indication for primary arthroscopic reconstruction.
- Voluntary agreement to participate in the study and signing of the informed consent form.

Exclusion criteria

- Patients with concomitant knee pathologies requiring additional surgical procedures in the same session.
- Presence of contraindications for ambulatory (day) surgery.
- Failure to adhere to the scheduled follow-up visits.

- Incomplete medical records regarding the implementation of ERAS protocol components (for the retrospective phase).

5. Sample size

The study utilizes the largest calculated sample size to ensure statistical power across all objectives. For the assessment of the Quality of Recovery (QoR-15), a cross-sectional sample of 115 patients was determined using a single mean estimation formula ($\alpha = 0.05$, $\sigma = 0.82$, $d = 0.15$). For the interventional phase, a power analysis performed via G*Power 3.1.9.4 indicated that a minimum of 54 patients (27 per group) is required to detect an effect size of 0.79 with 80% power at a 0.05 significance level. Consequently, the study aims to enroll at least 115 participants, comprising 68 elective surgery cases and 67 day-surgery cases.

6. Steps to conduct research

Phase 1: Status Assessment and Baseline Evaluation

- Conduct a retrospective cohort study to describe the ERAS implementation status in previous cases via medical records.
- Perform a cross-sectional descriptive study to evaluate the quality of postoperative recovery using the QoR-15 tool and knee function using the LKSS and the cost-effectiveness of treatment using the EQ-5D-5L tool.

Phase 2: Interventional Study and Effectiveness Evaluation

- Intervention Implementation: Apply 06 standardized ERAS measures to the patients
- Evaluate discharge readiness in the recovery unit using the Postanesthetic Discharge Scoring (PADS).
- Monitor and compare outcome variables between elective surgery and day-surgery groups, including recovery quality, complication rates, and cost-effectiveness.
- Collect data at specific intervals: Pre-op (T-1), 1-day post-op (T1), 1 month (T2), 3 months (T3), and 6 months (T4).
- Record the rate of patients requiring readmission within 7 days post-discharge.

7. Research Implementation plan (Gantt chart)

	12/25	4/2026-4/2027	05-06/27	07-12/27
Protocol				
Data collection				
Analyze data and present results				

	12/25	4/2026- 4/2027	05-06/27	07-12/27
Report				

8. References

- [1] Sanders TL, Maradit Kremers H, Bryan AJ, Larson DR, Dahm DL, Levy BA, et al. Incidence of Anterior Cruciate Ligament Tears and Reconstruction: A 21-Year Population-Based Study. *Am J Sports Med.* 2016;44(6):1502-7. Epub 20160226. doi: 10.1177/0363546516629944. PubMed PMID: 26920430.
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- [4] Lefevre N, Servien E, Colombet P, Cournapeau J, Dalmay F, Lutz C, et al. French prospective multicenter comparative assessment of ambulatory surgery feasibility in anterior cruciate ligament reconstruction. *Orthop Traumatol Surg Res.* 2016;102(8s):S257-s63. Epub 20160927. doi: 10.1016/j.otsr.2016.08.006. PubMed PMID: 27687062.
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