

# Study Protocol

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**Official Title:**

Evaluation of Pulmonary Function, Respiratory Muscle Strength, Peripheral Muscle Strength and Functional Capacity in Individuals Undergoing Minimally Invasive Cardiac Surgery

**NCT Number:**

Pending (to be updated once ClinicalTrials.gov assigns the NCT number)

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**Collaborating Institution:**

Gülhane Training and Research Hospital, Department of Cardiovascular Surgery

## **1. Background and Rationale**

Coronary artery bypass grafting (CABG) is a standard treatment for high-risk patients. While median sternotomy remains the common approach, minimally invasive cardiac surgery via mini-thoracotomy may reduce surgical trauma, infection risk, and recovery time. However, its effects on pulmonary function, respiratory muscle strength, peripheral muscle strength, and functional capacity are not well established. This study aims to compare these outcomes between minimally invasive and conventional sternotomy approaches.

## **2. Objectives**

Primary Objective:

- To compare changes in pulmonary function parameters (FVC, FEV1, PEF) from baseline to postoperative day 4 between the two surgical techniques.
- To compare changes in respiratory muscle strength (MIP, MEP)
- To compare changes in peripheral muscle strength (handgrip, shoulder flexion/abduction, hip flexion, knee extension)
- To compare changes in functional capacity (6-minute walk distance, 30-second sit-to-stand repetitions)

Secondary Objectives:

- To compare changes in pain (McGill Pain Questionnaire) and kinesiophobia (Tampa Scale of Kinesiophobia)

## **3. Study Design**

Type: Observational, prospective, two-group comparison

Population: Adults undergoing elective CABG via either minimally invasive approach or conventional sternotomy

Time Perspective: Prospective

Estimated Enrollment: 40 participants (20 per group)

Sampling Method: Consecutive sampling

## **4. Eligibility Criteria**

Inclusion Criteria:

- Adults aged 18–80 years
- Scheduled for elective CABG via minimally invasive approach or conventional sternotomy at Gülhane Training and Research Hospital
- Able to provide written informed consent

Exclusion Criteria:

- Previous history of cardiac surgery

- Orthopedic or neurological disorders affecting mobility or muscle strength
- Postoperative cerebrovascular event
- Mechanical ventilation > 24 hours postoperatively
- ICU stay > 48 hours
- Development of deep vein thrombosis during hospitalization

## 5. Study Procedures

Assessments will be performed twice:

- Baseline (preoperative)
- Postoperative day 4

Measurements:

- Pulmonary Function: Spirometry (FVC, FEV1, PEF)
- Respiratory Muscle Strength: MIP, MEP using mouth pressure device
- Peripheral Muscle Strength: Handgrip via dynamometer; shoulder flexion/abduction, hip flexion, knee extension
- Functional Capacity: 6-minute walk test, 30-second sit-to-stand test
- Pain: McGill Pain Questionnaire
- Kinesiophobia: Tampa Scale of Kinesiophobia

## 6. Outcome Measures

Primary Outcome:

- Change in pulmonary function (FVC, FEV1, PEF) from baseline to postoperative day 4
- Change in MIP, MEP
- Change in peripheral muscle strength
- Change in 6-minute walk distance
- Change in 30-second sit-to-stand repetitions

Secondary Outcomes:

- Change in McGill Pain Questionnaire score
- Change in Tampa Scale of Kinesiophobia score

## 7. Statistical Analysis Plan

Descriptive statistics will be calculated for demographic and baseline data.

- Normality testing will be performed using Kolmogorov-Smirnov test.
- Between-group comparisons: Independent t-test (parametric) or Mann-Whitney U test (non-parametric).
- Within-group changes (pre- vs post-operative): Paired t-test (parametric) or Wilcoxon signed-rank test (non-parametric).
- Categorical variables: Chi-square test.

- Significance level will be set at  $p < 0.05$ .
- Statistical analysis will be performed using SPSS version 24.0.

## **8. Ethical Considerations**

The study has been approved by Çankırı Karatekin University Ethics Committee. Written informed consent will be obtained from all participants. All personal data will remain confidential and used only for research purposes.