

STATISTICAL ANALYSIS PLAN (SAP)

Title: Effect of Enhanced Recovery After Cesarean (ERAS) Protocol on Mother–Infant and Father–Infant Bonding: A Multicenter Randomized Controlled Trial

Protocol Code: ERAS-CS-BOND-1

Principal Investigator: Dr. Gökçenur Karakelleoğlu

Institution: Istanbul Okan University Hospital

Country: Türkiye

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STATISTICAL ANALYSIS PLAN

1. Introduction

This Statistical Analysis Plan (SAP) describes all prespecified analyses for protocol ERAS-CS-BOND-1.

2. Study Objectives

Primary Objective:

To compare the effect of the Enhanced Recovery After Cesarean (ERAS) protocol versus standard perioperative care on mother–infant bonding as measured by the Postpartum Bonding Questionnaire (PBQ) total score on postpartum day 7.

Secondary Objectives:

1. To evaluate early maternal bonding (MIBS at 2 hours; PBQ at 24 hours and postpartum day 4).
2. To assess father–infant bonding on postpartum day 7 using the PBQ.
3. To compare maternal depressive symptoms between groups (EPDS at 2 hours and postpartum day 7).
4. To assess maternal recovery indicators (time to oral intake, time to mobilization, analgesic consumption, length of hospital stay).

5. To compare neonatal outcomes (Apgar scores; need for NICU admission).
6. To evaluate early breastfeeding indicators (time to first breastfeeding, duration of skin-to-skin contact).

3. Analysis Populations

- **Intention-to-treat (primary)**
- **Per-protocol (secondary)**
- **Safety population:** all randomized participants

4. Sample Size Justification

Cohen's $d = 0.35 \rightarrow n=134$ per arm

+10% loss $\rightarrow 150$ per arm

Total: 300 mothers

5. Statistical Methods

5.1 Descriptive Analysis

- Mean \pm SD, median (min–max)
- Frequencies (%)

5.2 Primary Outcome Analysis

PBQ Day 7 total score:

- Independent-samples t-test (if normal)
- Mann–Whitney U test (if non-normal)
- Effect size reported (Cohen's d)

5.3 Secondary Outcomes

- MIBS: t-test
- PBQ repeated measures: **Linear Mixed Models**
- EPDS: repeated measures LMM
- Neonatal outcomes: logistic regression
- Time variables: survival analysis where relevant

5.4 Handling of Missing Data

Multiple imputation using chained equations.

Sensitivity analyses will be performed.

5.5 Subgroup Analyses

- Primiparous vs multiparous
- Spinal vs general anesthesia