STUDY PROTOCOL

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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

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Country: Türkiye

Version: 1.0

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NCT Number: Not yet Assigned

1. STUDY SUMMARY

This multicenter, parallel-group, randomized controlled trial will compare the effect of Enhanced Recovery After Cesarean (ERAS) protocol versus standard perioperative care on mother–infant and father–infant bonding among women undergoing cesarean delivery. Initially, the study will begin at Istanbul Okan University Hospital, with additional centers joining after initial feasibility.

- **Primary Outcome:** Postpartum Bonding Questionnaire (PBQ) total score on postpartum day 7 (mother–infant bonding).
- **Secondary Outcomes:**
    - Maternal bonding: MIBS (2 hours), PBQ (24 hours, day 4, day 7)
    - Father–infant bonding: PBQ (day 7)
    - Maternal depressive symptoms: EPDS (2 hours, day 7)
    - Time to first breastfeeding, duration of skin-to-skin contact
    - Neonatal outcomes: NICU admission, Apgar scores
    - Maternal recovery: oral intake, mobilization time, analgesic needs, length of stay

Sample size: 300 mothers (150 ERAS, 150 standard care) and 300 fathers (optional participation).
Randomization: Block randomization, stratified by parity and anesthesia type.
Blinding: Outcome assessors and data analysts will be blinded.

2. BACKGROUND AND RATIONALE

Cesarean delivery rates continue to rise globally. ERAS, originally developed for colorectal surgery, has been adapted for obstetrics to enhance recovery, reduce opioid use, encourage early mobilization, shorten hospital stay, and improve patient satisfaction.

Evidence suggests that early skin-to-skin contact and early breastfeeding support mother–infant bonding and reduce postpartum depressive symptoms. Delays in mobilization, prolonged fasting, and opioid-heavy pain management can negatively affect maternal mood and bonding.

Father–infant bonding has been rarely studied, especially in the context of cesarean delivery, where paternal involvement may be limited.

To date, no randomized controlled trial in Türkiye has examined ERAS effects on **both maternal and paternal bonding**. This study aims to fill this gap.

3. STUDY OBJECTIVES

Primary Objective

To determine whether the ERAS protocol improves mother–infant bonding on postpartum day 7 compared with standard care.

Secondary Objectives

- Evaluate the impact of ERAS on father–infant bonding at day 7
- Assess early maternal bonding (MIBS at 2 hours; PBQ at 24 hours, day 4, day 7)
- Evaluate postpartum depressive symptoms (EPDS at 2 hours and day 7)

- Compare neonatal outcomes (NICU need, Apgar scores)
- Compare maternal recovery indicators (oral intake, ambulation, analgesia, length of stay)
- Evaluate maternal childbirth satisfaction and perceived self-efficacy

4. STUDY POPULATION

Inclusion Criteria

1. Women aged 18–50 years
2. Singleton, live fetus at ≥37 weeks
3. Elective or emergency cesarean delivery
4. Ability to read/understand Turkish
5. Willingness to complete follow-up assessments
6. Written informed consent from mother (and father, if participating)
7. Clinically stable postpartum condition

Exclusion Criteria

1. Preterm birth (<37 weeks)
2. Multiple pregnancy
3. Stillbirth or early neonatal death
4. Major congenital anomaly or prolonged NICU stay
5. Severe maternal complications (hemorrhage, hysterectomy, severe preeclampsia/eclampsia, severe infection)
6. Active psychiatric disorder or psychotropic medication
7. High-dose opioid need interfering with assessments
8. Cognitive impairment or inability to complete questionnaires
9. Withdrawal from study or inability to complete follow-up

5. STUDY DESIGN AND METHODS

Study Design

A parallel-group, randomized controlled, multicenter clinical trial.

Study Groups

1. **ERAS Group (Intervention):**
    - Shortened fasting
    - Carbohydrate loading
    - Multimodal opioid-sparing analgesia
    - Early oral intake
    - Early mobilization
    - Early urinary catheter removal
    - Immediate/early skin-to-skin contact
    - Early breastfeeding initiation
2. **Standard Care Group (Control):**
    - Routine perioperative management according to institutional protocol

Study Timeline

- **Before delivery:** Consent, demographics, obstetric history
- **2 hours postpartum:** MIBS, EPDS, early bonding indicators
- **24 hours postpartum:** PBQ, breastfeeding status
- **Day 4:** PBQ (phone or clinic)
- **Day 7:** PBQ (mother and father), EPDS, satisfaction scores

Randomization

1:1 allocation using computer-generated random blocks; stratified by

- Parity (primiparous vs multiparous)
- Planned anesthesia type (spinal vs general)

Blinding

- Outcome assessors: Blinded
- Data analysts: Blinded
- Participants/care providers: Not blinded (nature of intervention)

6. DATA COLLECTION

Standardized Case Report Forms (CRFs) will be used.
All data coded, stored securely for at least 15 years.
Source data verification and periodic monitoring will ensure accuracy.

7. SAFETY AND ETHICAL CONSIDERATIONS

- No additional medical risk expected
- Conducted under Helsinki Declaration and GCP
- Adverse events will be recorded and reported
- Participant confidentiality ensured per local regulations

8. REFERENCES

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