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Evaluation of postpartum depression in patients undergoing cesarean section managed with an ERAS protocol

Submission date
23/12/2025

Recruitment status
No longer recruiting

Registration date
29/12/2025

Overall study status
Completed

Last Edited
29/12/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Plain English summary of protocol not provided at registration.

Contact information

Type(s)
Principal investigator, Public, Scientific

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Study information

Scientific Title
Effect of ERAS protocol after cesarean section on postpartum depression: a randomized controlled trial

Study objectives

The Enhanced Recovery After Surgery (ERAS) protocol is an evidence-based, multidisciplinary approach that includes preoperative, perioperative, and postoperative interventions. These interventions aim to accelerate functional recovery and improve postoperative outcomes. The ERAS protocol seeks to minimize surgery-related complications and optimize the duration of recovery. By reducing preoperative fasting time, ensuring effective pain control, promoting early mobilization, and enabling early postoperative nutrition, ERAS attenuates surgery-induced catabolic and inflammatory responses. The ERAS protocol has been widely implemented across various surgical disciplines, including gynecologic oncology, benign gynecology, urology, and hepatobiliary surgery. Postpartum depression is reported to occur less frequently in populations undergoing normal vaginal delivery. In this study, we aimed to evaluate changes in postpartum depression questionnaire scores in patients who received the ERAS protocol after cesarean section compared with those who did not.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/03/2025, Düzce University Non-Interventional Health Research Ethics Committee (Konuralp, Düzce, 81620, Türkiye; +90 0850 800 81 81; duzceetik@duzce.edu.tr), ref: 2025/26

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Health services research, Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Evaluation of postpartum depression following ERAS implementation in patients undergoing cesarean section.

Interventions
Methods
Study Design
This study was designed as a prospective randomized controlled trial conducted in the Department of Obstetrics and Gynecology. The anticipated study duration is nine months.

Participants
Patients admitted to the Obstetrics and Gynecology clinic with an indication for cesarean section due to fetal or maternal reasons were eligible for inclusion. Only patients with a clear clinical indication for cesarean delivery were enrolled. No additional interventions beyond standard clinical care were performed.

Randomization
Eligible participants were randomly assigned to either the ERAS group or the control group using a computer-generated randomization program.

Interventions
Patients in the intervention group received postoperative care according to the Enhanced Recovery After Surgery (ERAS) protocol, while patients in the control group received standard postoperative care. No additional medications were initiated for study purposes. Preoperative, perioperative, and postoperative clinical data and pharmacological treatments were recorded for both groups.

Outcomes
Primary Outcomes
The primary outcomes were early postoperative recovery parameters, including:

Time to first postoperative flatus following cesarean delivery
Postoperative pain scores
Postoperative complications (wound complications, urinary retention, and postpartum hospital readmission)
Patient satisfaction

Secondary Outcomes
The secondary outcome was the assessment of postpartum anxiety and depression after discharge using the Edinburgh Postnatal Depression Scale (EPDS).

Outcome Measurements
Postpartum pain severity was assessed using the Visual Analog Scale (VAS), a 10-cm scale ranging from 0 (no pain) to 10 (severe pain). Patients were asked to rate their pain intensity, and scores were recorded.
Patient satisfaction was evaluated using a Likert scale (1 = poor, 5 = excellent).
VAS and satisfaction scores were collected by physicians during face-to-face ward visits.

Data Collection and Management
Patient identification data were not included in the study records. All collected data were stored in a computerized archive. After completion of data collection, outcomes were compared between the ERAS and control groups.

Ethical Considerations
No life-threatening risks were anticipated in this study. No procedures without clinical indication were performed, and no risk factors expected to harm participants were present. No additional medications were administered as part of the study.

Statistical Analysis
All study data will be analyzed using appropriate statistical methods.

Intervention Type

Other

Primary outcome(s)
1. Time to first postoperative flatus following cesarean delivery measured using postpartum pain scores and patient satisfaction scores at the time of cesarean delivery

2. Postpartum anxiety and depression after discharge measured using the Edinburgh Postnatal Depression Scale (EPDS) at the time of discharge

Key secondary outcome(s))

Completion date
18/12/2025

Eligibility

Key inclusion criteria
1. Patients with indications for cesarean section
2. 18-40 age pregnant woman
3. Without a prior diagnosis of psychiatric illness and without current or previous use of psychiatric medications

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
40 years

Sex
Female

Total final enrolment
150

Key exclusion criteria
1. Presence of preeclampsia or eclampsia
2. Pre-existing hypertension
3. Placental invasion anomalies
4. Placental abruption
5. Pregestational or gestational diabetes mellitus
6. Perioperative complications (including intraoperative bladder or bowel injury)
7. Orthopedic conditions that could limit postoperative mobilization

Date of first enrolment

01/04/2025

Date of final enrolment
08/12/2025

Locations

Countries of recruitment
Türkiye

Sponsor information

Organisation
Düzce Atatürk State Hospital

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date