

# Comparing the severity of postpartum depression in women who gave birth vaginally with or without an epidural

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| <b>Submission date</b><br>28/11/2018   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>17/12/2018 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>13/09/2021       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
|  |   | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

### Background and study aims

Depression after birth is a disorder of pregnant women, manifesting itself with a depressed mood, insomnia or somnolence, marked weight loss, psychomotor retardation, a lowered self-esteem and self-worth, and suicidal thoughts. To decrease the possible depression rates several approaches were studied. Epidural analgesia is one of them. Epidural analgesia is a commonly used method in the world to reduce the pain of the pregnant women during labor and is well tolerated by both the mother and the infant. In this study, our primary aim was that the women who had epidural labor analgesia would have lower depression severity scores in the sixth postpartum week. Our secondary aim was that those patients would have lower pain scores during the labor and in at 24th hour if they received epidural analgesia. Our study covered 6 months' time. The patients were assigned to two groups. One group consisted of the women who gave birth without receiving an epidural analgesia and the other group consisted of women who gave birth with epidural analgesia. Prior to birth and in the 6th week after birth, depression scales were administered to all patients. The patients' severity of the pain was assessed by scales the labor and in the 24th hour postoperatively. In conclusion, our study identified favorable pain scores and lower depression severity in the 6th weeks after birth for patients who received epidural analgesia. In addition, we reported that the increased scores of pains at labor were correlated with postpartum depression. In the light of these results, we suggest that pregnant women should prefer epidural analgesia if they are going to give birth via the normal vaginal route.

### Who can participate?

The women at 18-45 years of age, who would give birth electively via normal vaginal route with or without epidural analgesia, who had ASA scores of I-III, and who consented to participate were included in the study

### What does the study involve?

Patients were divided into two groups. One group consisted of the women who gave birth without receiving an epidural analgesia and the other group consisted of women who gave birth with epidural analgesia. Prior to birth and in the 6th week after birth, depression scales were

administered to all patients. The patients' severity of the pain was assessed by scales the labor and in the 24th hour postoperatively

What are the possible benefits and risks of participating?

There was no risk for the participants because it wats an observational study.

Where is the study run from?

İstanbul Education and Research Hospital, Istanbul (Turkey)

When is the study starting and how long is it expected to run for?

From 25/03/2018 to 25/10/2018

Who is funding the study?

İstanbul Education and Research Hospital, Istanbul

Who is the main contact?

Dr. İpek S. Edipoglu

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## Contact information

### Type(s)

Scientific

### Contact name

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34020

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

Scientific Title

A comparison of the severity of postpartum depression in women who gave normal vaginal birth with or without epidural analgesia: a prospective observational study

### **Study objectives**

Women who have epidural labour analgesia will have lower depression severity scores in the sixth postpartum week. Patients will have lower Visual Analogue Scale (VAS) scores in the 24th hour if they receive epidural analgesia during labour.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Istanbul Training and Research Hospital Anesthesiology department institutional ethics committee approved the study, 08/02/2018.

### **Study design**

Single centered, prospective, observational

### **Primary study design**

Observational

### **Secondary study design**

Cohort study

### **Study setting(s)**

Hospital

### **Study type(s)**

Diagnostic

### **Participant information sheet**

Not available in web format, please use the contact details below to request a participant information sheet'

### **Health condition(s) or problem(s) studied**

Postpartum depression

### **Interventions**

From the patients who agreed to participate, one group consisted of the women who gave birth without receiving an epidural analgesia and the other group consisted of women who gave birth with epidural analgesia. The total duration of observation and duration of the follow up was 6 weeks for all patient groups. Prior to birth and in the postpartum 6th week, Edinburgh postnatal depression scale was administered to all patients. The patients' severity of the pain was assessed by Visual analogue scale (VAS) during the labour and in the 24th hour postoperatively.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

**Primary outcome measure**

Edinburgh postnatal depression scale scores prior to birth and in the postpartum 6th week,

**Secondary outcome measures**

Visual Analogue Scale (VAS) scores during labour and at 24th hour

**Overall study start date**

25/02/2018

**Completion date**

25/11/2018

**Eligibility****Key inclusion criteria**

1. Women aged 18 to 45 years old.
2. Would give birth electively via normal vaginal route with or without epidural analgesia
3. ASA scores of I-III

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

88

**Total final enrolment**

92

**Key exclusion criteria**

1. History of schizophrenia, bipolar disorder or obsessive-compulsive disorder in the pre-partum period.
2. Haematological disorders contraindicated for regional anaesthesia.
3. Skin infections in the lumbar area.
4. If the route of delivery was required to be switched to a cesarean section.

**Date of first enrolment**

25/03/2018

**Date of final enrolment**

25/10/2018

# Locations

## Countries of recruitment

Türkiye

## Study participating centre

İstanbul eğitim ve araştırma hastanesi

Balıklı Kazlıçeşme Yolu Cd. No:1 Zeytinburnu

istanbul

Türkiye

34020

# Sponsor information

## Organisation

istanbul eğitim ve araştırma hastanesi

## Sponsor details

Telsiz Mahallesi, Balıklı Kazlıçeşme Yolu Cd. No:1, 34020 Zeytinburnu/İstanbul

istanbul

Türkiye

34020

## Sponsor type

Hospital/treatment centre

## ROR

<https://ror.org/00nwc4v84>

# Funder(s)

## Funder type

Other

## Funder Name

investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

### **Intention to publish date**

25/11/2019

### **Individual participant data (IPD) sharing plan**

The data sharing plans for the current study are unknown and will be made available at a later date.

### **IPD sharing plan summary**

Data sharing statement to be made available at a later date

### **Study outputs**

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 01/05/2021   | 13/09/2021 | Yes            | No              |