

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

Submission date 28/11/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/12/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/09/2021	Condition category 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 was 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?

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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

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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?
Results article		01/05/2021	13/09/2021	Yes	No