ISRCTN84174861 https://doi.org/10.1186/ISRCTN84174861

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

Registration date
17/12/2018

Overall study status
Completed

Last Edited
13/09/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
dripeks@yahoo.com

Contact information

Type(s)
Scientific

Contact name
Dr Ipek Saadet Edipoglu

ORCID ID
https://orcid.org/0000-0002-3510-5991

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

Additional identifiers

Protocol serial number
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

Study type(s)
Diagnostic

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

Key secondary outcome(s))
Visual Analogue Scale (VAS) scores during labour and at 24th hour

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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

ROR
https://ror.org/00nwc4v84

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes