Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Fear of childbirth in epidural analgesia and aromatherapy with lavender: a randomized two-arm parallel-group trial

Protocol summary

Study aim
Comparison of epidural analgesia and aromatherapy with lavender in terms of labor fear during and after delivery

Design
Single- center, not-blinded, two arm parallel group randomised superiority trial

Settings and conduct
Eligible women admitted to the maternity ward of Izadi Educational and Medical Center for vaginal delivery, after obtaining informed written consent, will be studied. There is no possibility for blinding due to nature of the interventions.

Participants/Inclusion and exclusion criteria
Participants will be primiparous or multiparous women with a maximum of two previous deliveries without a history of uterine surgery. Healthy sense of smell, 18 to 45 years old, alive cephalic single mature fetus, regular contractions, dilatation 4 to 5 centi-meters, no previous sedation in 4 hours before intervention, and low-risk pregnancy are eligibility criteria. Those with any contraindications for vaginal delivery, abnormal amniotic fluid volume, non-reactive fetal heart rate, any contraindications to epidural analgesia or aromatherapy, pregnancy with ART, major physical or mental illness, severe obesity, unwillingness to participate in the study will be excluded from the study.

Intervention groups
In the aromatherapy group, we will place a piece of sterile cotton fabric (with length and width about15 centimeter), impregnated with 0.1 milliliters of lavender essential oil prepared by Barij Essential Oil Company diluted with 1 milliliter of distilled water on the patient's neck. In the epidural group, intermittent injection technique will be performed by an anesthesiologist, according to the national protocol of painless delivery. Depending on the patient's need and pain, every 30 to 60 minutes, 5 to10 milliliter of bupivacaine 0.125 to 0.0625% or rupivacaine 0.1 to 0.2% will be repeated.

Main outcome variables
Intensity of fear during labor and after delivery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100414003706N39**
Registration date: **2021-08-23, 1400/06/01**
Registration timing: **prospective**

Last update: **2021-08-23, 1400/06/01**
Update count: **0**

Registration date
2021-08-23, 1400/06/01

Registrant information

Name
Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3477 2699

Email address
alizades@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-05, 1400/06/14

Expected recruitment end date
2022-03-05, 1400/12/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Fear of childbirth in epidural analgesia and aromatherapy with lavender: a randomized two-arm parallel-group trial

Public title
Comparison of epidural analgesia and aromatherapy with lavender regarding fear of childbirth

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Have a healthy sense of smell Age 18 to 45 years First to third childbirth Live single fetus with cephalic presentation Gestational age 37 to 41 weeks regular labor contractions Cervical dilatation 4 to 5 cm No received sedation in 4 hours prior to intervention Having a low-risk pregnancy (absence of third trimester bleeding, placental abruption, placenta previa, fetal growth disorder, etc.)

Exclusion criteria:
Any surgery on the uterus including cesarean section Any contraindications to vaginal delivery including Cephalopelvic disproportion (CPD) Abnormal amniotic fluid volume Any contraindications to receive epidural analgesia or aromatherapy, including a history of allergies to herbal or analgesic drugs Pregnancy with the help of assisted reproductive techniques (ART) Any major physical or mental illness Severe obesity (Body mass index (BMI) higher than 35 kilograms per square meter) Unwillingness to participate in the study or the inability to obtain informed consent from the person, including having excessive anxiety or stress Non-reactive fetal heart rate

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be individually randomized into intervention or control groups using stratified (previous history of labor and type of labor onset (spontaneous or induction)) block randomization with block size of four and six. Allocation sequence will be determined using a computerized program (www.random.org). Sequentially numbered opaque sealed envelopes will be used to conceal the allocation. Allocation sequence and the envelopes will be prepared by a person not involved in participant recruitment and allocation, or data collection.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Ave., Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2021-08-02, 1400/05/11

Ethics committee reference number
IR.TBZMED.REC.1400.414

Health conditions studied

1

Description of health condition studied
Fear during and after childbirth

ICD-10 code
F40.232

ICD-10 code description
Fear of other medical care

Primary outcomes

1

Description
childbirth fear

Timepoint
One and two hours after intervention

Method of measurement
Delivery Fear Scale

2

Description
Severity of postpartum fear

Timepoint
Two hours and 5 weeks after delivery

Method of measurement
Wijma Version B scale

Secondary outcomes

1

Description
pain intensity
Timepoint
At 4 to 5 cm cervical dilatation (just before intervention), 30 minutes after the intervention and then every hour until delivery.
Method of measurement
Visual analog scale

2

Description
childbirth experience satisfaction
Timepoint
12 to 24 hours after delivery
Method of measurement
Birth satisfaction scale-revised questionnaire

3

Description
duration of the first, second and third stages of labor and intervention until delivery
Timepoint
beginning to the end of intervention
Method of measurement
Partograph

4

Description
Emergency cesarean section
Timepoint
beginning to the end of intervention
Method of measurement
Researcher observation

Intervention groups

1

Description
Intervention group 1: In the epidural group, the injection will be performed by an anesthesiologist according to the national protocol for painless delivery, and with the intermittent injection technique. In this technique, depending on the patient's needs and pain, 5 to10 milliliter of bupivacaine 0.125 to 0.625% or rupivacaine 0.1 to 0.2% will be repeated every 30 to 60 minutes.
Category
Other

2

Description
Intervention group 2: In the aromatherapy group, a piece of linen cloth (with length and width about 15 centemeter), impregnated with 0.1 milliliter of lavender essential oil prepared by Barij Essential Oil Company, diluted with 1 milliliter of distilled water, is placed on the patient's neck. Linen fabric is used to preserve the scent and the skin does not absorb the essential oil and prevent complications. Fabrics will be stored in sterile conditions.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Izadi Educational and Medical Center
Full name of responsible person
Dr. Mohammad Javad Hakim Elahi
Street address
Izadi Hospital and Maternity Hospital, Azar St., after the gas station, Qom
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Qom
Province
Ghoum
Postal code
3713649373
Phone
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ezadi-hospital@muq.ac.irn
Web page address
https://izadi.muq.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Samiei
Street address
No. 2 Central building of the university, Golgasht street, Azadi street
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Phone
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Email
research-vice@tbzmed.ac.ir
Web page address
https://researchvice.tbzmed.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Zohreh Zakavi
Position
MSc student in midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Professor
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Person responsible for updating data

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Position
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Latest degree
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Other areas of specialty/work
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mhammadalizadehs@gmail.com
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Requested data will be provided to researchers for statistical analysis (meta- analysis) of the submitted proposal.
When the data will become available and for how long

starting immediately after publication of the study results

To whom data/document is available

Data will be available to researchers working at academic organizations, as well as to chief editor (and reviewers) of the journal of the submitted manuscript/s, if requested.

Under which criteria data/document could be used

The data will be available to researchers upon request and submission of a proposal to perform meta-analysis using IPD data after being unidentified. Also, in exceptional cases, data will be made available to journal of submitted manuscript/s for checking accuracy of the dat

From where data/document is obtainable

Refer to the email address (alizades@tbzmed.ac.ir; mhammadalizadehs@gmail.com)

What processes are involved for a request to access data/document

The requests will be sent by email and data will be available within a week.

Comments