Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Determining the effect of pharmacological and non-pharmacological analgesia on Childbirth fear, experience and postpartum depression: a randomized controlled clinical trial

Protocol summary

Study aim

The effect of non-pharmacological analgesia and pharmacological analgesia with remifentanil on childbirth fear, experience and postpartum depression

Design

The present study is a randomized clinical trial with two parallel arms. Sampling on pregnant women aged 18-45 years admitted to Taleghani Medical Training Center where the participants were rationed based on the number of deliveries with 4 and 6 blocks with a ratio of 1: 1 to the two groups receiving Remi analgesic Fentanyl and non-pharmacological analgesia will be assigned. Data analysis will be performed using SPSS-Version 24 software. The analysis will be performed by Intention to treat method

Settings and conduct

Sampling on pregnant women aged 18-45 years admitted to Taleghani Medical Training Center where the participants were rationed based on the number of deliveries with 4 and 6 blocks with a ratio of 1: 1 to the two groups receiving Remi analgesic Fentanyl and non-pharmacological analgesics will be assigned. Pain and fear during labor are measured in 8 cm dilatation in both groups. Fear of childbirth in the postpartum period will be measured one month after delivery using Vijama B, postpartum experience, and postpartum depression.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 45-18 years. Living in the city of Tabriz.Gestational age 42-37 weeks Not included in the study: Multiple pregnancies. Having chronic or induced or a

Intervention groups

In the group of painless drug delivery, remifentanil injection in dilation 4-6 cm to complete dilation

Main outcome variables

Comparison of the mean score of fear during labor and postpartum between two groups receiving drug analgesia with remifentanil and non-drug analgesia Fear of labor in labor using labor (DFS) and fear of labor in the postpartum period using version B of Vijama, They will be measured one month after delivery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170506033834N10**
Registration date: **2022-07-05, 1401/04/14**
Registration timing: **prospective**

Last update: **2022-07-05, 1401/04/14**
Update count: **0**

Registration date

2022-07-05, 1401/04/14

Registrant information

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Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-06, 1401/05/15

Expected recruitment end date

2022-10-07, 1401/07/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determining the effect of pharmacological and non-pharmacological analgesia on Childbirth fear, experience and postpartum depression: a randomized controlled clinical trial

Public title
The effect of pharmacological and non-pharmacological analgesia during childbirth
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
En Women with first and second pregnancies Age 45-18 years Living in the city of Tabriz Tendency to deliver with remifentanil analgesia and non-drug analgesia Gestational age 42-37 weeks
Exclusion criteria:
Multiple pregnancies Chronic or induced or aggravated diseases in pregnancy such as hypertension, cardiovascular disease, diabetes, preeclampsia, etc. Indications for cesarean section such as placenta previa, non-cephalic presentations, abnormal fetal heartbeats, etc. . Having a history of depression based on self-expression or taking anti-anxiety and anti-depressant medications Occurrence of a significant stressful incident in the family during the last 6 months, such as the death of a loved one, separation from a spouse and ... History of cesarean section or uterine incision Abnormal pregnancy trends such as polyhydramnios, oligohydramnios, intrauterine growth disorder Body mass index 35 and above Hospitalization in dilatation after 6 cm Unplanned pregnancy incision Tendency to use other methods of analgesia History of attending physiological delivery classes
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **33**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will then be randomly assigned to two groups receiving remifentanil analgesic and non-pharmacological analgesia using RAS(Random Allocation Software) based on the number of deliveries (1 or 2) with 4 and 6 blocks with a ratio of 1: 1. In order to hide the allocation (Allocation Concealement), opaque envelopes are numbered in a row, which will be used as a type of intervention written on paper. Envelopes will also be prepared and randomly assigned by the non-involved person.
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
Third Floor of Research and Technology Vice-Chancellor, Central Building No. 2/ Tabriz University of Medical Sciences/ Golgasht Street /Tabriz
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Tabriz
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East Azarbaijan
Postal code
5165665931
Approval date
2022-06-01, 1401/03/11
Ethics committee reference number
IR.TBZMED.REC.1401.231

Health conditions studied

1

Description of health condition studied
Postpartum depression
ICD-10 code
O90.6
ICD-10 code description
Postpartum mood disturbance

Primary outcomes

1

Description
Score of Fear of chilbirth from Wijma and Delivery Fear Scale(DFS) questionnaires
Timepoint
Fear during labor will measured at 8 cm dilatation and one month after delivery
Method of measurement
Fear of childbirth in labor using the Delivery Fear Scale

(DFS) Measures fear of childbirth. During labor, the researcher reads the ten statements of the scale aloud. The woman responds orally to each phrase with a number between 1 and 10 (1 = "I do not agree at all", 10 = "Strongly agree"; total score 10 to 100). The higher the score, the greater the fear. After starting the intervention, 8 cm dilatation will be completed by the participants through interviews. Cronbach's alpha coefficient for DFS structures in Iran (0.77) has been calculated, which indicates the desired internal compatibility. In other studies, this scale had a Cronbach's alpha coefficient of 0.91, which is similar to the results of Wijma et al. (33).) Will be measured. The WDE-Q (B) questionnaire was designed by Wijma et al. To measure the severity of fear of childbirth in the postpartum stage. Mothers rate their feelings and personal cognition on a 6-point Likert scale from 0 to 5. In general, the score obtained is the sum of the scores of all items. The range of scores is between zero and 165. A score less than or equal to 37 indicates low fear, a score of 38 to 65 indicates moderate fear, a score equal to or greater than 66 indicates high fear, and a score above 85 indicates severe fear. (34) The higher the fear of childbirth, the higher the score. This questionnaire will be completed at the time of hospitalization. The validity and reliability of this questionnaire in Iran has been confirmed by Mortazavi et al. Cronbach's alpha coefficient is set at 0.914 (51)

2

Description

Score of Child birth experience in childbirth experience questionnaire (SEQ-2.0)

Timepoint

Childbirth experience will be measured one month after delivery

Method of measurement

Thechilbirth experience will be measured using the Childbirth Experiences Questionnaire version 2.0 (CEQ-2.0). This questionnaire, which was designed by Dencker et al., contained 23 questions in a 4-point Likert scale. In this tool, the questions answered on a visual scale are converted into values from 1 to 4: scores 0-40 (score 1), scores 41-60 (score 2), 61-80 (score 3), 81-100 (score 3). score 4). Sentences with negative connotations (experiencing severe pain, feeling tired, fear and having a bad memory) are scored negatively. High average scores in this tool mean a more positive experience of childbirth . This questionnaire will be completed by the participants one month after giving birth. The validity and reliability of this questionnaire in Iran has been confirmed by Ghanbari Homai et al. The reliability of the questionnaire was determined by Cronbach's alpha method of 0.93 and the intraclass correlation coefficient was determined as 0.97.

3

Description

score of postpartum deppresion from the Edinburgh Depression Questionnaire

Timepoint

Postpartum depression will be measured one month after delivery

Method of measurement

Postpartum depression is measured using the Edinburgh Depression Questionnaire. This tool has 10 four-choice questions, each question has a score of 0 to 3 and the total score ranges from 0 to 30. The mother chooses the answers that she felt during the last week that the minimum score in this tool is zero and the maximum score is 30, and a score of 12 and above is considered depression. Validity and reliability of this questionnaire in Montazeri's study has been confirmed in Iran. The reliability of the questionnaire was determined by Cronbach's alpha method of 0.77 and by test method at 0.8.

Secondary outcomes

1

Description

score of childbirth pain

Timepoint

Score of childbirth pain during labor

Method of measurement

To measure the intensity of pain, the VAS: Visual Analogue scale is used, which is the same as the pain ruler.

2

Description

The duration of the first, second and third stage of labor

Timepoint

The duration of the first, second and third stage of labor during labor

Method of measurement

The duration of the first, second and third stage of labor during labor with in hours or minutes.

3

Description

Apgar score of baby

Timepoint

Apgar score in first and fifth minute

Method of measurement

Apgar score in first and fifth minute with apgar scale

4

Description

frequency of Postpartum hemorrhage

Timepoint

Postpartum hemorrhage in the first 24 hours

Method of measurement

Postpartum hemorrhage based on document

5

Description

Frequency ofcesarian

Timepoint

Delivery Type after chilbirth

Method of measurement

Frequency ofcesarian based on document

Intervention groups

1

Description

Intervention group: In the group of painless drug delivery in dilation of 4-6 cm, remifentanil will be performed by an anesthesiologist according to the national protocol of painless delivery using a continuous intravenous infusion pump at a dose of 0.05 µg / kg / min. After dilation is complete, ie in the second stage of labor, the infusion will be stopped

Category

Treatment - Drugs

2

Description

Control group: For the non-pharmacological analgesia group in the active phase of labor, lumbar massage, lukewarm abdominal shower, pressure on the sacrum, breathing techniques and upright positions are used.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Parinaz Masroor

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Taleghani Hospital, Railway Square, Tabriz, East Azerbaijan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

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

Esmat Mehrabi

Position

Ph.D in reproductive health

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
خیر
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available