

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of breastfeeding success rate in mothers under painless delivery by epidural anesthesia with normal vaginal delivery

Protocol summary

Study aim

Comparison of suckling success rate in mothers with analgesia (epidural anesthesia) with normal delivery

Design

Clinical trial with two groups of 150, in parallel, by random sampling method, using randomized software (Rand list online)

Settings and conduct

Comparison of suckling success rate in mothers with analgesia (epidural anesthesia) with normal delivery in the delivery department of Taleghani Hospital in Tabriz

Participants/Inclusion and exclusion criteria

Inclusion criteria: First-born women with single-dose pregnancies ;Pregnancy up to 37 weeks ;Demand for labor with epidural ; Healthy baby Exclusion criteria: Multicultural women ; Lack of lactation or scientific indication ; Embryonic anomalies or metabolic diseases that make it impossible to breastfeed ; Missing pregnant woman for epidural anesthesia ; APGAR score less than 7 ; Asafixy baby

Intervention groups

The intervention group included women with epidural method, receiving bupivacaine 0.12% 125/0% or rupivacaine 0.1-0.2% + fentanyl 51 µg per 10-15 ml volume. The control group includes women with normal delivery that do not receive intervention

Main outcome variables

Nausea, headache, back pain, respiratory depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160103025821N7**

Registration date: **2019-06-13, 1398/03/23**

Registration timing: **prospective**

Last update: **2019-06-13, 1398/03/23**

Update count: **0**

Registration date

2019-06-13, 1398/03/23

Registrant information

Name

Hojjat Pourfathi

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 1994

Email address

pourfathih@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-20, 1398/03/30

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of breastfeeding success rate in mothers under painless delivery by epidural anesthesia with normal vaginal delivery

Public title

success rate in mothers under painless delivery by epidural anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

single baby nulliparous woman, Pregnancy up to 37 weeks;
Demand for labor with epidural; Healthy baby

Exclusion criteria:

multi-parity; no willing to lactation, Embryonic anomalies
or metabolic diseases that make it impossible to
breastfeed; no willing to lactation, insatis fact for
epidural anesthesia APGAR score less than 7; Asafixy
baby

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients were Simple random assigned into two
groups using randomized computer data to two
treatment groups: (100) Patients in the analgesia group
and (100) patients in the control group will be included in
the study. Will be grouped by research experts using
random numbers tables.

Blinding (investigator's opinion)

Double blinded

Blinding description

The questionnaire is filled in by the midwife and will be
recorded by the student (blind).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of the research and technology
department, Tabriz University of Medical sciences

Street address

Research department, Daneshgah street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166615953

Approval date

2019-05-07, 1398/02/17

Ethics committee reference number

IR.TBZMED.REC.1398.131

Health conditions studied

1

Description of health condition studied

Lactation success rate

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hypotension

Timepoint

Immediately after the intervention, after 5 minute, after
10 minute, after 20 minute, after 40 minute, after 60
minute, after 1.5 hour, after 2 hour, after 3 hour, ...

Method of measurement

Monitoring, Sphygmomanometer tool

2

Description

Backpain

Timepoint

Immediately after the intervention, after 5 minute, after
10 minute, after 20 minute, after 40 minute, after 60
minute, after 1.5 hour, after 2 hour, after 3 hour, ...

Method of measurement

History

3

Description

Respiratory depression

Timepoint

Immediately after the intervention, after 5 minute, after
10 minute, after 20 minute, after 40 minute, after 60
minute, after 1.5 hour, after 2 hour, after 3 hour, ...

Method of measurement

PHysical examination

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group included women with epidural
method, receiving bupivacaine 0.12% 125/0% or
rupivacaine 0.1-0.2% + fentanyl 51 µg per 10-15 ml

volume.
Category
Rehabilitation

2

Description

Control group: Natural childbirth

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان طالقانی تبریز

Full name of responsible person

دکتر حجت پورفاتی

Street address

Taleghani hospital, Rah ahan square, Tabriz

City

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34424882

Phone

+98 41 3442 4425

Email

pourfathih@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. abolghasem jouyban

Street address

Tabriz University of Medical Sciences, Daneshgah
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3344280 0413

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ajouyban@hotmail.com

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

Dr. Hojjat Pourfathi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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No32,University Ave, Opposite the Central Office of
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Hojjat Pourfathi

Position

Associate Professor

Latest degree

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Person responsible for updating data

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Full name of responsible person
Dr. Hojjat Pourfathi
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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City
Tabriz
Province
East Azarbaijan
Postal code

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available