

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparing effect of the neuraxial painless vaginal delivery with vaginal delivery on fetal outcomes with due attention to newborns' APGAR scores in first, fifth and tenth minutes

Protocol summary

Summary

In current non-randomized, non-blinded single center study, we aim to evaluate neonates' APGAR scores in first, fifth and tenth minutes, seeking for cardiopulmonary resuscitation, need for neonatal intensive care unit admission, alterations in fetal heart rate, breastfeeding time, discharge time and neonatal reflexes in first day of birth in both painless and normal vaginal delivery groups. In current interventional study, 300 women admitted to delivery room of the Taleghai hospital divided to two groups. Women who are capable to perform vaginal delivery and gave their informed consent, will enroll study. In addition, patients who cannot remain immobile during procedure and do not provide consent to participate in study, excluded. One of the neuraxial painless delivery methods such as spinal, epidural and combined spinal-epidural, selected for each patient with due attention to woman parity and delivery phase and APGAR scores during first, fifth and tenth minutes will be recorded in a designed questionnaire. Afterward, using Mann Withney U statistical test, statistical differences between groups will be obtained.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010325821N1**
Registration date: **2016-07-14, 1395/04/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-14, 1395/04/24

Registrant information

Name

Hojjat Pourfathi

Name of organization / entity

Tabriz university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and development of Tabriz University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-07-20, 1395/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of the neuraxial painless vaginal delivery with vaginal delivery on fetal outcomes with due attention to newborns' APGAR scores in first, fifth and tenth minutes

Public title

Newborns first, fifth and tenth minutes APGAR scores during painless delivery using neuraxial analgesia compared to normal vaginal delivery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: There is a possibility of natural birth;
There is labor pain and active delivery phase; mother's consent to reduce delivery pain; spouse consent.
Exclusion criteria: mother's disinclination to participate;
Inability to maintain immobility during procedure;
Coagulation disorders and defects in homeostasis;
Increased intracranial pressure for any reason; Frank infection at the needle site; Hypersensitivity to local anesthetics or other medications using in this methods;
Acute lesions of the central nervous system; Maternal hemodynamic instability (hypovolemia, hypotension);
Heart diseases that cardiac output is severely limited;
fetal distress.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 the research and technology department, Tabriz University of Medical sciences

Street address

Research department- Daneshghah street- Tabriz

City

Tabriz

Postal code

Approval date

2016-02-08, 1394/11/19

Ethics committee reference number

IR.TBZMED.REC.1394.1039

Health conditions studied

1

Description of health condition studied

Delivery pain and its effect on fetal health condition

ICD-10 code

P04.0

ICD-10 code description

Fetus and newborn affected by maternal anaesthesia and analgesia in pregnancy, labour and delivery

Primary outcomes

1

Description

pain

Timepoint

before the intervention, Immediately after the intervention, Every 5 minutes until delivery, Immediately after delivery

Method of measurement

visual analogue scale tool

2

Description

Apgar

Timepoint

first, fifth and tenth minutes after birth

Method of measurement

Apgar scoring system

3

Description

Fetal heart rate

Timepoint

before the intervention, Immediately after the intervention, Every 5 minutes until delivery, Immediately after delivery

Method of measurement

physical examination

Secondary outcomes

1

Description

hypotension

Timepoint

before the intervention, immediately after the intervention, every 5 minutes until delivery, immediately after delivery

Method of measurement

Sphygmomanometer tool

2

Description

Oxygen saturation level

Timepoint

before the intervention, immediately after the intervention, every 5 minutes until delivery, immediately

after delivery
Method of measurement
pulse oximeter

3

Description
The first time of breastfeeding
Timepoint
Immediately after delivery
Method of measurement
Physical examination

4

Description
pain
Timepoint
before the intervention, immediately after the intervention, every 5 minutes until delivery, immediately after delivery
Method of measurement
visual analogue scale tool

Intervention groups

1

Description
Neuraxial method: during delivery 25 to 50 microgram intrathecal fentanyl injection as opioid combined with 2.5 milligram bupivacaine to enhance analgesia quality and duration
Category
Prevention

2

Description
Control group: vaginal delivery will be performed without intrathecal opioid injection.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Taleghani hospital
Full name of responsible person
Dr. Hojjat Pourfathi
Street address
Taleghani hospital, Rah ahan square, Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Rashidi
Street address
Tabriz University of Medical Sciences, Daneshgah Street, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research of Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Medicine faculty
Full name of responsible person
Hassan Soleiman Pour
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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

Assistant Professor in Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Hojjat Pourfathi

Position

Assistant Professor in Anesthesiology

Other areas of specialty/work

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