Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Determination of adequacy of analgesia and satisfaction of vaginal delivery women with persistent intravenous analgesia with remifentanil infusion and comparing it with epidural analgesia

Protocol summary

Study aim
Determination of adequacy of analgesia and satisfaction of vaginal delivery women with persistent intravenous analgesia with remifentanil infusion and comparing it with epidural analgesia

Design
This study is a randomized clinical trial (with three phases) with parallel groups that will be conducted with the participation of 65 women who are not blind during the study.

Settings and conduct
Women with vaginal delivery referred to Al-Zahra Hospital in Tabriz after random assignment. The women in the intervention group (remifentanil group) will dissolve 4 mg remifentanil in 100cc normal saline solution (40 µg/ml) and the drug will be infused through the infusion pump at a speed of 2 to 4 cc/h. Women in the control group were also implanted under sterile epidural catheter conditions and bolus doses of analgesia containing 15 to 10 ml of marcain 0.650 solution and 15 to 20 µg of fentanyl injected after catheter placement with continuous infusion of the infusion pump containing 100cc of the solution containing mercury 0.650 plus 300 to 400 micrograms of fentanyl is infused at a rate of 4 to 6 ml per hour depending on the severity of the patient's pain.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Perform vaginal delivery Exclusion criteria: Candidate for cesarean section

Intervention groups
Women candidates for vaginal delivery will be studied in accordance with inclusion and exclusion criteria after random assignment to control and intervention groups. The women in the intervention group will receive remifentanil intravenously and the women in the control group will receive marcaine through epidural anesthesia. Then the severity of the pain will be compared.

Main outcome variables
Pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190325043107N14**
Registration date: **2019-12-15, 1398/09/24**
Registration timing: **prospective**

Last update: **2019-12-15, 1398/09/24**
Update count: **0**

Registration date
2019-12-15, 1398/09/24

Registrant information
Name
Mehdi Khanbabayi Gol
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-01-05, 1398/10/15
Expected recruitment end date
2020-12-20, 1399/09/30
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of adequacy of analgesia and satisfaction of vaginal delivery women with persistent intravenous analgesia with remifentanil infusion and comparing it with epidural analgesia

Public title

Determination of adequacy of analgesia in vaginal delivery with persistent intravenous analgesia with remifentanil compared to epidural analgesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Perform vaginal delivery

Exclusion criteria:

Women candidates for cesarean section

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: **65**

Randomization (investigator's opinion)

Randomized

Randomization description

With the help of a randomization list provided by the online statistical software www.randomizer.org, they will be placed into one of two intervention or control groups, respectively.

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

Azadi Ave, Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2019-12-16, 1398/09/25

Ethics committee reference number

1158

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

F45.4

ICD-10 code description

Pain disorders related to psychological factors

Primary outcomes

1

Description

Pain

Timepoint

Every hour for two days

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group women (Remifentanil group) will dissolve 4 mg Remifentanil in 100cc normal saline solution (40µg/ml) and the drug will be infused through infusion pump at a rate of 2 to 4 cc/h . Pain measurement will be done every hour for two days using visual analogue scale.

Category

Treatment - Other

2

Description

Control group: Women in the control group were also implanted under sterile epidural catheter conditions and bolus doses of analgesia containing 15 to 20 ml of marcain 0.650 solution and 15to 20 µg of fentanyl injected after catheter placement with continuous infusion of the infusion pump containing 1cc of the solution containing mercury 0.650 plus 300 to 400 micrograms of fentanyl is infused at a rate of 4 to 6 ml per hour depending on the severity of the patient's pain.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra
Full name of responsible person
Farnaz Moslemi
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Alzahra Hospital, Imam Khomeini Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Tabriz University of Medical Sciences
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Person responsible for updating data

Contact
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Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

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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