Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of analgesic effect of remifentanil with and without dexamethasone in labor

Protocol summary

Study aim
Comparison of analgesic effect of remifentanil with and without dexamethasone in labor
Design
In this interventional study, 100 pregnant women who are candidates for natural childbirth will be selected and divided into two groups using block randomization method (n=50 in each group). Proper counseling will be done and a written informed consent will be obtained before starting the treatment regimen.
Settings and conduct
Upon starting the active phase of labor intervention group will receive intravenous Remifentanil 0.05 µg/kg/min (Tofigh Daru Co.) and 8 mg intravenous Dexamethasone (once, 2 cc, Irandaroo Co.) injection and control group receive intravenous Remifentanil 0.05 µg/kg/min (Tofigh Daru Co.) and placebo (distilled water, 2 cc, Irandaroo Co., once) injection.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Over 37 weeks pregnancy, first or second pregnancy, singleton. Exclusion criteria: Malpresentation of fetus، macrosomia.
Intervention groups
Intravenous Remifentanil 0/05 µg/kg/min (Tofigh Daru Co.) and 8 mg intravenous Dexamethasone (once, 2 cc, Irandaroo Co.) injection. Control group: Intravenous Remifentanil 0/05 µg/kg/min (Tofigh Daru Co.) and placebo (distilled water, 2 cc, Irandaroo Co., once) injection.
Main outcome variables
pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150808023559N16**
Registration date: **2018-03-10, 1396/12/19**
Registration timing: **prospective**

Last update: **2018-03-10, 1396/12/19**
Update count: **0**
Registration date
2018-03-10, 1396/12/19

Registrant information
Name
Somaieh Matin
Name of organization / entity
Ardabil University of Medicine Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-19, 1397/01/30
Expected recruitment end date
2018-06-20, 1397/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of analgesic effect of remifentanil with and without dexamethasone in labor

Public title
Labor pain relief with remifentanil
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Over 37 weeks pregnancy First or second pregnancy Singleton

Exclusion criteria:

Malpresentation of fetus Macrosomia

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned randomly by blocking in one of the two specified groups and after selecting the envelope for each patient, before starting the treatment regimen envelope will be opened and based on the protocol, one of two methods will be selected.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and clinical caregivers are not aware of the type of medication

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Ardabil University of Medicine Sciences, Daneshgah street, Ardabil

City

Ardabil

Province

Ardabil

Postal code

5615783134

Approval date

2017-12-31, 1396/10/10

Ethics committee reference number

IR.ARUMS.REC.1396.189

Health conditions studied

1

Description of health condition studied

Labor pain

ICD-10 code

O80, O84

ICD-10 code description

Delivery

Primary outcomes

1

Description

pain

Timepoint

Before analgesic administrations and two times (30 and 60 min) after intervention

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Apgar

Timepoint

1 and 5 minutes after birth

Method of measurement

Apgar test

Intervention groups

1

Description

Intervention group: Intravenous Remifentanil 0/05 µg/kg/min (Tofigh Daru Co.) and 8 mg intravenous Dexamethasone (once, 2 cc, Irandaroo Co.) injection

Category

Treatment - Drugs

2

Description

Control group: Intravenous Remifentanil 0/05 µg/kg/min (Tofigh Daru Co.) and placebo (distilled water, 2 cc, Irandaroo Co., once) injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alavi Hospital

Full name of responsible person
Somaieh Sagafi rad

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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?
Yes

Title of funding source
Ardabil 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
Ardabil University of Medical Sciences

Full name of responsible person
Somaieh Sagafi rad

Position
Gynecology Asisstant

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Associate professor

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Specialist

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Person responsible for updating data

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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