

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison effect of Entonox and Dexamethasone versus Remifentanil and Dexamethasone on the control of painless delivery

Protocol summary

Study aim

Efficacy of Entonox and Dexamethasone with Remifentanil and Dexamethasone in Controlled Pain.

Design

Control group clinical trial, with parallel, double-blind, randomized groups.

Settings and conduct

Ardebil Alavi Hospital

Participants/Inclusion and exclusion criteria

The study participants were the first pregnant mothers.

Intervention groups

In this study, 100 pregnant women were randomly assigned into A and B groups among first pregnant women referred to Hospital.

Main outcome variables

Promote painless delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190924044865N1**

Registration date: **2019-12-30, 1398/10/09**

Registration timing: **retrospective**

Last update: **2019-12-30, 1398/10/09**

Update count: **0**

Registration date

2019-12-30, 1398/10/09

Registrant information

Name

Zahra Asdagh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 937 688 4241

Email address

zahra.asdagh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2019-12-20, 1398/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of Entonox and Dexamethasone versus Remifentanil and Dexamethasone on the control of painless delivery

Public title

Comparison effect of Entonox and Dexamethasone

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

First Pregnancy Term pregnancy Without illness

Exclusion criteria:

preterm labor multipar

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is randomized blocking. Patients in groups A and B are placed in quadratic blocks (two patients in group A and two patients in group B). There will be a draw and the blocks will continue to be completed until the number of samples is 100.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, clinical outcome evaluator caregivers are kept blind. And they have no information about whether or not to take the medicine.

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

Shahid Motahari Street, Alavi Hospital

City

Ardebil

Province

Ardabil

Postal code

۵۶۱۸۹۸۵۹۹۱

Approval date

2019-06-22, 1398/04/01

Ethics committee reference number

IR.ARUMS.REC.1398.248

Health conditions studied

1

Description of health condition studied

Painful delivery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score

Timepoint

30, 60, 120, 180 minutes

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group (A): This group includes pregnant women receiving entonox and dexamethasone. In this group, after reaching the active phase of labor, the patient is advised to inhale one or two puffs of Entonex gas by mask each time he / she is given 8 mg of dexamethasone at the same time as Entonex gas.

Category

Treatment - Drugs

2

Description

Second Intervention Group (B): This group includes pregnant women receiving remifentanil and dexamethasone. In this group, after reaching the active phase of delivery, dexamethasone is administered 8 mg intravenously, along with remifentanyl opioid administered by the pain pump at a concentration of 1.5 mg per 100 ml serum at 14 cc / h. Starts.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi Hospital

Full name of responsible person

Giti Rahimi

Street address

Shahid Motahari Street

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5613974156

Phone

+98 45 3324 8888

Email

zahra.asdagh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

شهاب بهلولی

Street address

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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

Zahra Asdagh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Ardabil University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

Assistant Professor

Latest degree

Specialist

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