

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparative evaluation of the efficacy of Entonox Gas analgesia alone and in combination with magnesium sulfate in painless delivery in multipar mild preeclampsic patient

Protocol summary

Study aim

Comparative evaluation of the efficacy of Entonox Gas analgesia alone and in combination with magnesium sulfate in painless delivery in multipar mild preeclampsic patient 2019-2020

Design

This evaluation is a phase 3 clinical trial with a control group with parallel, not blinded and not randomized groups, accordingly, 35 people will be evaluated in each group.

Settings and conduct

This study was carried out as a clinical trial at the Ali ibn Abi Talib Hospital, also the study will not be blinded.

Participants/Inclusion and exclusion criteria

Pregnant women with preeclampsia, gestational age of 38 to 42 weeks, single fetus with cephalic presentation, in early active phase of labor, having normal fetal heart pattern, 60 to 80 kg weight, having no heart problems and other internal diseases, aged 20 to 40 years will be considered as study groups. Samples with unconsciousness disorder and poisoning, maxillofacial surgery in the last month, internal ear obstruction, fetal distress, unstable hemodynamic status, airway dysfunction, maternal gastric emptying and neuropsychiatric disorder will be excluded from study.

Intervention groups

In intervention group, mothers with start of pain, gas inhalation Entonox will start and soon overcome the pain, gas inhalation by the mother stops, mothers receive gas to second stage of labor. Also normal saline is given in a similar dose with a bolus dose of magnesium sulfate and then 20 cc infusions.

Main outcome variables

Pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200302046666N1**

Registration date: **2020-04-04, 1399/01/16**

Registration timing: **prospective**

Last update: **2020-04-04, 1399/01/16**

Update count: **0**

Registration date

2020-04-04, 1399/01/16

Registrant information

Name

Nikoo Ziyae

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3878 7391

Email address

ziyae.nn@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-07, 1399/01/19

Expected recruitment end date

2021-03-09, 1399/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of the efficacy of Entonox Gas analgesia alone and in combination with magnesium sulfate in painless delivery in multipar mild preeclampsic patient

Public title

Compare entonox alone and in combination with magnesium sulfate in painless delivery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant woman Preeclampsia Gestational age between 38 to 42 weeks Single pregnancy with cephalic presentation Being at the beginning of the active phase of labor Having a normal fetal heart pattern Weight 60 to 80 kg Not having heart problems and other internal diseases Age 20 to 40 years

Exclusion criteria:

Consciousness and poisoning disorder Maxillofacial surgery in the last month Internal ear obstruction Fetal distress Unstable hemodynamic status Airway Disorder Mother's stomach full Neurological and mental disorder

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

9816743463, Zahedan University of Medical Sciences, Dr. Hesabi Square, Persian Gulf Blvd, Zahedan, Sistan and Baluchestan

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Province

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Postal code

9816743463

Approval date

2019-10-12, 1398/07/20

Ethics committee reference number

IR.ZAUMS.REC.1398.405

Health conditions studied

1

Description of health condition studied

Preeclampsia

ICD-10 code

O15.0

ICD-10 code description

Eclampsia in pregnancy

Primary outcomes

1

Description

Pain

Timepoint

During delivery

Method of measurement

Using visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mothers with start of pain, gas inhalation Entonox will start and soon overcome the pain, gas inhalation by the mother stops, mothers receive gas to second stage of labor.

Category

Treatment - Drugs

2

Description

Control group: In this group, normal saline is given in a similar dose with a bolus dose of magnesium sulfate and then 20 cc infusions.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ibn Abi Talib Hospital

Full name of responsible person

Nikoo Ziyae

Street address

9816743463, Ali Ibn Abi Talib Hospital, Dr. Hesabi Square, Persian Gulf Blvd, Zahedan, Sistan and Baluchestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mohammad Reza Shahraki

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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

Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Nikoo Ziyae

Position

Resident of Anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Anesthesiologist

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Specialist

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Person responsible for updating data

Contact**Name of organization / entity**

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Position

Anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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