Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparative evaluation of the efficacy of Entonox Gas analegesia 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 analegesia 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 onsciousness 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 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 Ziyaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3878 7391

Email address

ziyaee.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 analegesia 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
City
Zahedan
Province
Sistan-va-Balouchestan
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 Ziyaee

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 Ziyaee

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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Position
Anesthesiologist

Latest degree
Specialist

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Anesthesiology

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Person responsible for updating data

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Specialist
Other areas of specialty/work
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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