Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of analgesic effect of inhaling Entonox with and without paracetamol in labor

Protocol summary

Study aim
Evaluation of the efficacy of Entonox inhalation alone and in combination with paracetamol in controlling normal labor pain

Design
Group A (50 cases) will receive intravenous paracetamol at a dose of 1 gram and Entonox inhalation, and Group B (50 cases) will receive normal saline (50 cases) and Entonox inhalation. Patients undergo continuous pulse oximetry and FHR monitoring.

Settings and conduct
Questionnaire included age, weight, maternity records, type of analgesia, fetal heart rate, duration of active phase of labor, duration and intervals of uterine contractions, neonatal apgar score at first and fifth minutes, pain score before and after analgesia and The side effects in each case will be completed by the female resident. Patients' vital signs, including blood pressure, heart rate and respiratory rate before and after analgesia, and visual analogue score (VAS) were measured every 30 minutes.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Single pregnancy (41 - 37 weeks) - Onset of active phase of labor - Cephalic presentation - Absence of fever or serious systemic disease - Absence of fetal distress - Absence of meconium Exclusion criteria: Existence of fetal distress - presence of meconium

Intervention groups
The group will be anesthetized by intravenous paracetamol injections of 1 g and inhaled Entonox.

Main outcome variables
Score pain before and after prolonged analgesia and uterine contractions intervals, first and fifth minute neonatal apgar score,

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190915044779N1**
Registration date: **2019-09-30, 1398/07/08**
Registration timing: **retrospective**

Last update: **2019-09-30, 1398/07/08**
Update count: **0**

Registration date
2019-09-30, 1398/07/08

Registrant information

Name
Rogayye Dargahi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 45 3323 0739

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z.noori@arums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
2018-09-23, 1397/07/01

Actual recruitment end date
2019-03-20, 1397/12/29

Trial completion date
2019-03-20, 1397/12/29

Scientific title
Comparison of analgesic effect of inhaling Entonox with and without paracetamol in labor

Public title
Comparison of analgesic effect of inhaling Entonox with and without paracetamol in labor
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Single pregnancy (41 - 37 weeks) Onset of active phase of labor Cephalic presentation Absence of fever or serious systemic disease Absence of fetal distress Absence of meconium Age 14 to 40 years
Exclusion criteria:
Pregnancy hypertension Gestational diabetes
Age
From **14 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Not randomized
Randomization description
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 Ardabil University of Medical Sciences
Street address
No. 1, Moallem Ave
City
Ardabil
Province
Ardabil
Postal code
5613843785
Approval date
2018-08-31, 1397/06/09
Ethics committee reference number
IR.ARUMS.REC.1397.069

Health conditions studied

1

Description of health condition studied
Labor pain
ICD-10 code
O47.0
ICD-10 code description
False labor before 37 completed weeks of gestation

Primary outcomes

1

Description
The main outcome variable in this study is pain.
Timepoint
The beginning of the delivery process and then every 30 minutes until delivery is complete.
Method of measurement
The VAS is a pain measurement scale in which a person scores from 0 to 10. 0 means no pain and 10 means the worst pain one can imagine.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The group will be anesthetized by intravenous paracetamol injections of 1 gr and inhaled Entonox.
Category
Treatment - Drugs

2

Description
Control group: The group will receive intravenous administration of normal saline and inhaled Entonox.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alavi hospital
Full name of responsible person
Zahra Noori
Street address
No. 1, Moallem Ave
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Ardabil
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Parvane Naftchi
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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
Rogayye Dargahi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Questionnaires and case number will be provided to the university research unit. And the SPSS file will be published.
When the data will become available and for how long
Immediately upon completion of thesis
To whom data/document is available
University professors
Under which criteria data/document could be used
The information will be anonymous to protect patients' privacy.
From where data/document is obtainable
Contact Dr. Dargahi's Email.
What processes are involved for a request to access data/document
Request via email to Dr. Dargahi then confirmation from Ms. Parvaneh Naftchi (Thesis Officer of Ardabil University of Medical Sciences)
Comments