Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of paracetamol with Entonox in comparison with pethidine with Entonox on labor pain

Protocol summary

Study aim

we decided to conduct a study with the aim of investigating the effect of paracetamol with Entonox in comparison with pethidine with Entonox in reducing pain during NVD, so that if this combined method is more effective, it will be a step towards creating a better experience of childbirth.

Design

Clinical trial without control group , with parallel groups , Two blind strains , Randomized , on 100 patients , Statistical software was used for randomization.

Settings and conduct

Qazvin Kosar hospital Single blind Data analysts do not know the type of drug used 100 pregnant women who meet the inclusion criteria will be included in the study and Pain intensity will be measured at six times.

Participants/Inclusion and exclusion criteria

Patients should be between 18 and 45 years old. The fetal presentation should be cephalic. Fetuses are single. Dilatation of the uterus should be 4 cm. Do not have fetal growth disorders. Have no history of chronic pain. Do not be addicted to drugs, alcohol or cigarettes. Have no indication for cesarean section. Have no history of severe psychological disorders, cardiovascular, renal, respiratory, asthma, diabetes, hypertension, coagulation disorders and epilepsy.

Intervention groups

first Intervention group: Infusion of acetaminophen, 1g, in 100cc of N/S, with 300 gtt/min + entonox gass inhalation second Intervention group: Infusion of pethidin, 50 mg, in 100cc of N/S, with 300 gtt/min + entonox gass inhalation

Main outcome variables

Labor pain score ;The time between drug injection and delivery ; placenta delivery time ; newborn Apgar score ; mother hemoglobin level ; Drug side effects in the mother

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220116053734N1**
Registration date: **2022-12-08, 1401/09/17**
Registration timing: **prospective**

Last update: **2022-12-08, 1401/09/17**
Update count: **0**

Registration date

2022-12-08, 1401/09/17

Registrant information

Name

Ensiyeh Rajabpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3356 7131

Email address

ensiehr8@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of paracetamol with Entonox in comparison with pethidine with Entonox on labor pain

Public title
Evaluation of the effect of paracetamol with Entonox in comparison with pethidine with Entonox on labor pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients should be between 18 and 45 years old. The fetal presentation should be cephalic. Fetuses are single. Dilatation of the uterus should be 4 cm.
Exclusion criteria:
Having a fetal growth disorder Having a history of chronic pain Having an addiction to drugs, alcohol and smoking Having indications for cesarean section Havind a history of severe psychological disorders, cardiovascular, renal, respiratory, asthma, diabetes, hypertension, coagulation disorders and epilepsy in mother
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are assigned to two treatment groups A and B using the balanced block randomization method through https://www.sealedenvelope.com/simple-randomiser/v1/lists. The size of each block is 4 and the total number of blocks is 25. Balanced randomization allocation for the participants in the current study, the effect of Paracetamol with Entonox (A) and Pethidine with Entonox (B) on labor pain is investigated.
Blinding (investigator's opinion)
Single blinded
Blinding description
Checklist information is provided by the secretary of the department in which people with file number are registered to the person responsible for the analysis and statistical analysis of the plan. After entering SPSS and coding 1 and 2, the results of the evaluation will be analyzed by the statistician, separated into paracetamol receiving and pethidine receiving groups (which only the secretary of the department knows about). Therefore, the researcher and evaluator are not aware of the trend of pain during labor, and the statistician is not aware of which analgesic drug the patient received. The data analyst and the safety monitoring committee are not aware of which drugs the patients took.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences
Street address
Kosar hospital, Taleghani st, Valiasr Blvd
City
Qazvin
Province
Qazvin
Postal code
3414763804
Approval date
2021-05-29, 1400/03/08
Ethics committee reference number
IR.QUMS.REC.1400.100

Health conditions studied

1

Description of health condition studied
Pain during labor
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Labor pain score
Timepoint
before drug injection and 15, 30, 45, 60 and 120 minutes after drug injection
Method of measurement
pain NRS numerical rating scale

Secondary outcomes

1

Description
The time between drug injection and delivery
Timepoint
Drug injection time and fetus delivery time
Method of measurement
time

2

Description
placenta delivery time
Timepoint
delivery time and placenta delivery time
Method of measurement
time

3

Description
newborn Apgar score
Timepoint
1 and 5 minutes after labor
Method of measurement
Apgar score

4

Description
mother hemoglobin level
Timepoint
Before delivery and 6 hours after delivery
Method of measurement
Hemoglobin

5

Description
Drug side effects in the mother including headache/dizziness/blurred vision/dry mouth/nausea/vomiting/dyspnea
Timepoint
During the time of drug injection until delivery
Method of measurement
Ask the patient

Intervention groups

1

Description
first Intervention group: Infusion of acetaminophen, 1 g, 6.7 ml, Caspian company, in 100cc of N/S, with 300 gtt/min + entonox gass inhalation
Category
Treatment - Drugs

2

Description
second Intervention group: Infusion of pethidin, 50 mg, 1 ml, Exir company, in 100cc of N/S, with 300 gtt/min + entonox gass inhalation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar hospital
Full name of responsible person
Ensiyeh Rajabpour
Street address
Kosar hospital, Taleghani st, Valiasr Blvd
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ensiehr8@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Seyyed Mehdi Mirhashemi
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Qazvin university of medical science, Bahonar Blvd
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3419759811
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medicine@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences

Full name of responsible person
Ensiyeh Rajabpour
Position
student
Latest degree
A Level or less
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
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
Yes - There is 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
Title and more details about the data/document
Patient unidentifiable individuals data and the final clinical study report can be released.
When the data will become available and for how long
Releasing after one year of publication of the study results
To whom data/document is available
Academic-scientific institutions
Under which criteria data/document could be used
The use of data and results is permitted for future scientific research.
From where data/document is obtainable
Receive data by email to the researcher ensiehr8@gmail.com
What processes are involved for a request to access data/document
About a month after sending the request
Comments