Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of Hyoscine butylbromide effects on pain severity of first stage of labor and fetal heart rate in multiparous women

Protocol summary

Study aim
Evaluation of Hyoscine butylbromide effects on pain severity of first stage of labor and fetal heart rate in multiparous women

Design
Phase 2-3 randomized clinical trial with parallel groups which will be conducted on 100 women during the labor

Settings and conduct
This study will be conducted with the aim of evaluation of Hyoscine butylbromide effects on pain severity of first stage of labor and fetal heart rate in 100 multiparous women. After inclusion in the study, using block randomization method with blocks of ten, the patients will be assigned into two groups; intervention group receiving 20 mg Hyoscine (1 ml) intravenously and control group receiving 1 ml normal saline. The injections in both groups will be intravenously and during the active phase of labor. Pain severity will be measured by Visual Analog Scale (VAS) and Fetal Heart Rate will be measured by using a specific device and will be compared together.

Participants/Inclusion and exclusion criteria
Age of 18-35; Singleton pregnancy; Not having pregnancy complications such as gestational diabetes; Gestational age of 37-42 weeks

Intervention groups
Intervention group: Receiving 20 mg hyocine (1 ml) intravenously during the active phase of labor Control group: Receiving 1 ml normal saline intravenously during the active phase of labor

Main outcome variables
Pain severity of first stage of labor; Fetal Heart Rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180424039407N1**

Registration date: **2018-07-04, 1397/04/13**

Registration timing: **retrospective**

Last update: **2018-07-04, 1397/04/13**

Update count: **0**

Registration date

2018-07-04, 1397/04/13

Registrant information

Name
Afra Pazhouhi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3329 5715

Email address
a.pazhouhi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Hyoscine butylbromide effects on pain severity of first stage of labor and fetal heart rate in multiparous women

Public title

Evaluation of Hyoscine butylbromide effects on pain

severity of first stage of labor and fetal heart rate in multiparous women

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 18-35 Singleton pregnancy Not having pregnancy complications such as gestational diabetes Gestational age of 37-42 weeks

Exclusion criteria:
Cardiovascular disease Hypo- or hyperthyroidism Preeclampsia

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
block randomization with blocks of ten Considering the sample size of 100, 10 blocks with 10 cards (5 cards for each group) will be selected; by selecting each block, 5 patients will be assigned into each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drug and placebo will be coded as A and B and will be similar in shape so the patient and the caregiver (patient's physician) will be blinded.

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
Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9916789547

Approval date
2017-10-29, 1396/08/07

Ethics committee reference number
IR.ZAUMS.REC.1396.213

Health conditions studied

1

Description of health condition studied
Delivery

ICD-10 code
O80

ICD-10 code description
Encounter for full-term uncomplicated delivery

Primary outcomes

1

Description
Pain severity of first stage of labor

Timepoint
During the first stage of labor

Method of measurement
By using Visual Analog Scale (VAS)

2

Description
Fetal Heart Rate

Timepoint
During the full labor time

Method of measurement
By using a sonicaid device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving 20 mg Hyoscine (1 ml) intravenously during the active phase of labor

Category
Treatment - Other

2

Description
Control group: Receiving 1 ml normal saline intravenously during the active phase of labor

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali Ebne Abi Taleb Hospital
Full name of responsible person
Afra Pazhouhi
Street address
Khalije Fars Blv, Zahedan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Mohsen Taheri
Street address
Vice chancellor for research, Zahedan University of Medical Sciences, Zahedan
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Dr.Taheri@zaums.ac.ir

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
Afra Pazhouhi
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for updating data

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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