

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9916789547

Phone

+98 54 3329 5715

Email

Afrapazhouhi@gmail.com

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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5721

Email

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

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

Phone

+98 54 3329 5715

Email

Afrapazhouhi@gmail.com

Person responsible for scientific 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

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

Phone

+98 54 3329 5715

Email

Afrapazhouhi@gmail.com

Person responsible for updating data

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

Street address

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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9916789547

Phone

+98 54 3329 5715

Email

Afrapazhouhi@gmail.com

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