

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of intravenous Hyoscine-N-butylbromide on active phase labor pain in primigravid women

Protocol summary

Summary

This study was a double blind randomized clinical trial. The aim of this study was to evaluate the effect of Hyoscine-N-butylbromide on severity of pain during active phase of labor in primipara. 105 primigravid women with spontaneous labor were divided randomly in two groups of case and control. Either 40 mg of Hyoscine-N-butylbromide or placebo (2 ml normal saline) was injected intravenously at the beginning of active phase labor. Severity of pain was evaluated with VAS before injection and at times of 10, 20, 30, 60 and 120 minutes after injection. Duration of the first, second and third stages of labor, adverse maternal effect and APGAR score were secondary outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080423444N1**

Registration date: **2015-08-11, 1394/05/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-11, 1394/05/20

Registrant information

Name

Zahra Pahlavani Sheikhi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2015-04-09, 1394/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intravenous Hyoscine-N-butylbromide on active phase labor pain in primigravid women

Public title

The effect of intravenous Hyoscine-N-butylbromide on active phase labor pain in primigravid women

Purpose

Treatment

Inclusion/Exclusion criteria

Term pregnancy (37-42 weeks), pregnancy with a single live fetus, cephalic presentation, intact membrane, enter in the active phase of labor(cervical dilatation of 4 cm) with uterine contraction (at least 3 contraction lasting 40-60 seconds in 10 minutes), estimated fetal weight between 2500-4500 gr and absence of contraindication for vaginal delivery were the criteria for inclusion. The women with chronic induced illnesses, severe prepartum hemorrhage, preeclampsia, emergency cesarean section, prior uterine scar and the need to use other methods of analgesia (epidural analgesia or other opioids) were evicted from the study.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics committee of Zahedan University of
Medical Sciences

Street address

Pardis University of Medical Sciences Campus,
Hessabi Sq

City

zahedan

Postal code

9816743463

Approval date

2013-02-28, 1391/12/10

Ethics committee reference number

91-1967

Health conditions studied**1****Description of health condition studied**

Labor pain

ICD-10 code

O80.0

ICD-10 code description

Spontaneous vertex delivery

Primary outcomes**1****Description**

labor pain

Timepoint

before injection and at times of 10, 20, 30, 60 and 120
minutes after injection

Method of measurement

Visual analogue scale

Secondary outcomes**1****Description**

length of active phase

Timepoint

durind of first stage of labor

Method of measurement

examination

2**Description**

Duration of second stage of labor

Timepoint

During second stage of labor

Method of measurement

examination

3**Description**

Duration of third stage of labor

Timepoint

During third stage of labor

Method of measurement

examination

4**Description**

Apgar score

Timepoint

at 1st and 5th minutes

Method of measurement

examination

Intervention groups**1****Description**

40 mg intravenous hyoscine single dose

Category

Treatment - Drugs

2**Description**

2ml normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ibn Abi Talib hospital

Full name of responsible person

Zahra Pahlavani Sheikhi

Street address

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Taheri

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Pardis University of Medical Sciences Campus,
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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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty