Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 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

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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 membrance, 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
lenght 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, Hessabi Sq
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Zahedan
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

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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