Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Hyoscine - N - Butyl Bromide suppository on labor pain and process in nuliparous women

Protocol summary

Summary

To find out the effect of Hyoscine - N - Butyl Bromide suppository on labor pain and process this study was down on 130 nulliparous term pregnant women who came to Ahwaz Sina hospital due to the beginning of spontaneous labor pain in 2009. The samples were divided randomly into groups of case (n=65) and control (n=65). A Hyoscine suppository (20 mg) was given to case group and a placebo suppository was given to control group in the beginning of active phase of labor rectally. Then the labor pain, cervical dilatation and effacement progress and active phase and second stage duration and delivery type were recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138804282204N1**
Registration date: **2010-02-10, 1388/11/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-02-10, 1388/11/21

Registrant information

Name

Somayeh Makvandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Ahwaz Jondishapur University of Medical Sciences

Expected recruitment start date

2009-07-03, 1388/04/12

Expected recruitment end date

2009-10-22, 1388/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Hyoscine - N - Butyl Bromide suppository on labor pain and process in nuliparous women

Public title

The effect of Hyoscine -suppository on labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1.age 18-35 2. gestational age: 37-42 by LMP or under 26 weeks by sonography 3.single fetus 4. cephalic presentation 5.cervical dilatation= 3-4 cm 6. Cervical effacement = 30-60% 7.bishop score>7 8.spontaneous uterine contractions in the form of 3 contractions with 40 minutes duration per 10 min 9.minimum education= grade 5 at primary school. Exclusion criteria : 1.vaginal bleeding 2.abnormal fetal heart rate 3.neonatal body weight<2500 or >4000 gr 4.fetal abnormality or death 5.high risk pregnancy 6.history of uterine surgery 7.mother's tachycardia 8.history of medical disorder in mother 9.oxytocin infusion in labor stages 10.use of Narcotic or anodyne drug or other pain reliever methods 11.delivery in 2 hours from onset of study 12.Athletic mothers 13.addict mothers 14.Corporation in pre-labor education classes

Age

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

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **130**

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
Ahwaz Jondishapur University of Medical Sciences

Street address
Golestan

City
Ahwaz

Postal code

Approval date
1388-03-12, 769/01/-737

Ethics committee reference number
U-88242

Health conditions studied

1

Description of health condition studied
Labor pain

ICD-10 code
O80.0

ICD-10 code description
spontaneus vertex delivery

2

Description of health condition studied
Labor process

ICD-10 code
O80.0

ICD-10 code description
spontaneus vertex delivery

Primary outcomes

1

Description
labor pain

Timepoint
each 0.5 h

Method of measurement
visual analog scale

2

Description
cervical dilatation

Timepoint
each 1 h

Method of measurement
examination

3

Description
cervical effacement

Timepoint
each 1 h

Method of measurement
examination

4

Description
labor active phase duration

Timepoint
at the end

Method of measurement
observation

5

Description
labor second stage duration

Timepoint
at the end

Method of measurement
observation

6

Description
delivery type

Timepoint
at the end

Method of measurement
observation

Secondary outcomes

1

Description
neonatal Apgar score

Timepoint

at 1st and 5th minutes
Method of measurement
Examination & Ovservation

2

Description
maternal blood pressure
Timepoint
each 0.5 h
Method of measurement
examination

3

Description
fetal heart rate
Timepoint
each 0.5 h
Method of measurement
examination

4

Description
maternal pulse rate
Timepoint
each 0.5 h
Method of measurement
examination

Intervention groups

1

Description
hyoscine suppositiry 20 mg single dose
Category
empty

2

Description
placebo suppository
Category
empty

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Street address
City
Ahwaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research vice chancellor of Ahwaz jondishapour university of medical sciences
Full name of responsible person
Dr Mostafa Feghhi
Street address
Golestan
City
Ahwaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research vice chancellor of Ahwaz jondishapour 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
Name of organization / entity
Ahwaz jondishapour university of medical scienses
Full name of responsible person
Somaye Makvandi
Position
Master of science at midwifery
Other areas of specialty/work
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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Somaye Makvandi

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

Fax

Email

Web page address

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