

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 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

+98 916 604 2247

Email address

s-makvandi@ajums.ac.ir

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

spontaneous vertex delivery

2**Description of health condition studied**

Labor process

ICD-10 code

O80.0

ICD-10 code description

spontaneous 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 Fegghi

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 sciences

Full name of responsible person

Somaye Makvandi

Position

Master of science at midwifery

Other areas of specialty/work

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Full name of responsible person

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Other areas of specialty/work

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Full name of responsible person

Somaye Makvandi

Position

Other areas of specialty/work

Street address

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Phone

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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