

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The effect of intramuscular Hyoscine and Hyoscine-Promethazine on the duration of labour and delivery outcomes to nulliparous pregnant women (triple-blind randomized control trial)

Protocol summary

Summary

This study has been designed for assessment of effects of Hyoscine and Hyoscine-Promethazine on duration of labor and maternal, fetus and newborn outcomes. In this study our inclusion criteria will be 213 nulliparous women with/without abort in Zanjan hospitals. This study will be triple-blind (blinding of outcome assessor, patients and investigator) and will be three groups. The first group will receive 20mg(1ml) Hyoscine with 2ml distilled water(DW)(total 3ml), the second group 20mg(1ml) Hyoscine with 25mg(1ml) Promethazine+1ml DW(total 3ml) and third group(control group) 3ml DW. Major outcomes will include to duration of active phase of labor(dilatation 4-5cm and effacement 50-60% to full dilation), maternal outcomes (kind of vaginal delivery(operative delivery, epiziotomy with or without rupture) rupture of delivery channel(1-4 degree), cervical laceration and uterine atonia) and fetal outcomes (tachycardia, bradycardia, loss bite to bite variability and deceleration fetal heart rate)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512163027N29**

Registration date: **2016-02-07, 1394/11/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-07, 1394/11/18

Registrant information

Name

Fahimeh Sehhatie Shafaie

Name of organization / entity

Tabriz university of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-04-29, 1395/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intramuscular Hyoscine and Hyoscine-Promethazine on the duration of labour and delivery outcomes to nulliparous pregnant women (triple-blind randomized control trial)

Public title

Hyoscine and Hyoscine-Promethazine effects on the delivery

Purpose

Supportive

Inclusion/Exclusion criteria

37-41 weeks for gestational age; beginning uterus contraction spontaneous; 4-5 for dilatation; 50-60% for effacement; rupture amniotic sac before intervention but

not more than 6h past from its rupture; one twin; nulliparous(with/without abortion in previous pregnancy); lack of problem and sick in this pregnancy(for example preeclampsia, diabet,...); lack of controandication for normal delivery(HSV, CPD, placenta previa,...); lack of problem in fetuse(unormal presentation); normal BMI in this pregnancy; fetus weight in normal range(2500-4000) according sonography or clinical exam; lack of major hip tightness; cephalic presentation; major height at least 150cm; mather age(18-35) lack of glocome in mather(according to mathers statement); outgoing criteria(sensitivity to Hyoscine, unwillingness to continiue investigation, unormalfetus presentation, epidural analgsia)

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **213**

Randomization (investigator's opinion)

Randomized

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

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tabriz medical university

Street address

central building, Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz

City

tabriz

Postal code

5165665931

Approval date

2015-12-07, 1394/09/16

Ethics committee reference number

TBZMED.REC.1394.833

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

delivery

ICD-10 code

O80.9

ICD-10 code description

Single spontaneous delivery, unspecified

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

Kind of vaginal delivery, rapture of delivery canal without episiatomy, cervical laceration and uterus atonia

Timepoint

since begining intervention to 2 hours after birth

Method of measurement

check list

2**Description**

total of first stage of delivery

Timepoint

since intervention to birth

Method of measurement

timer

3**Description**

tachycardia, bradycardia, lost of beat to beat variability and long time deseleration in FHR

Timepoint

Since intervention to birth

Method of measurement

use of CTG

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

Total time for second and third stage of delivery

Timepoint

since camplet dilatation to delivery and exit plasenta

Method of measurement

timer

2**Description**

1 and 5 appgars, need to revival, the severityof jaundice if admitted to NICU

Timepoint

since delivery to releasing mather

Method of measurement

check list

3

Description

giddiness, dizziness, tachycardia, lips dryness, flushing of face, headache, nausea,

Timepoint

from intervention to 2 hours after delivery

Method of measurement

check list

Intervention groups

1

Description

(Ampul Hyoscine 20mg + 2cc distilled water) (total 3cc)

Category

Treatment - Drugs

2

Description

Ampul Hyoscine 20mg(1cc) plus
Promethazine 25mg(1cc) plus 1 cc distilled water (total 3cc)

Category

Treatment - Drugs

3

Description

distilled water 3 cc

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital in Khodabande city

Full name of responsible person

Dr Fatemeh Khanmohammadi

Street address

Amiralmomenin hospital, Shafa Stret, Khodabande, Zanzan

City

Khodabande

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

doc Mohammad Reza Rashidi

Street address

Center building of Tabriz Medical University, Golgasht Streat, Azadi Streat, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Nursing and Midwifery Faculty

Full name of responsible person

Farzane Shahmohammadi

Position

faculty of midwifery student

Other areas of specialty/work

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Fahime Sehhatie Shaffaee

Position

Master degree

Other areas of specialty/work

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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