

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of oral hyoscine on cervix status (Bishop score) in term pregnancy

Protocol summary

Study aim

Evaluation of the effect of oral hyoscine on improvement of Bishop score in first term pregnancy

Design

One hundred primiparous women referred to the Obstetrics and Gynecology Clinic of Mahdiah Hospital of Tehran were divided into two groups of oral administration of hyoscine and control (expected treatment) using randomized number table, according to the order of entry.

Settings and conduct

After obtaining a clinical history and vaginal examination of the participants, Bishop score is also calculated and recorded. Then the patients are randomly divided into two groups: hyoscine and control. At the time of admission for delivery, Bishop score is again calculated and recorded. During the course of the study, all patients were followed up by telephone, finally Bishop score, delivery time, rate late term or prolonged pregnancy, type of delivery, and neonatal characteristics were compared between the two groups.

Participants/Inclusion and exclusion criteria

Age over 18 years, primiparous, gestational age 39 weeks, 0 days to 40 weeks and 0 days, spontaneous pregnancy, single pregnancy, cephalic presentation, absence of placenta previa or placental detachment (decollement), Bishop score equal to or less than 5, absence Fetal distress, absence of IUGR or macrosomal infant (embryo weighing more than 4000 gr), no underlying disease, such as diabetes or pre-pregnancy or pregnancy hypertension, no history of cervical trauma, cervical surgery or uterine surgeries, absence of hyoscine susceptibility, no use of narcotics or analgesics, no glaucoma, no cardiovascular disease, or tachycardia with more than 100 beats per minute

Intervention groups

Group 1: taking oral hyoscine 10 mg twice daily for one week and then once a day in the second week at entering to the study (39-40 weeks) Group 2 (control):

Expected treatment

Main outcome variables

Cervix status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180819040830N1**

Registration date: **2018-11-24, 1397/09/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-24, 1397/09/03**

Update count: **0**

Registration date

2018-11-24, 1397/09/03

Registrant information

Name

Zahra Naeiji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5506 2628

Email address

z.naeigi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of oral hyoscine on cervix status (Bishop score) in term pregnancy

Public title
Evaluation of the effect of oral hyoscine on the rate of cervical opening in term pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age older than 18 years Primiparous Gestational age of 39 weeks and 0 days to 40 weeks and 0 days
 Spontaneous pregnancy Singleton pregnancy Cephalic presentation Bishop score equal to or less than 5
Exclusion criteria:
 The existence of a placenta previa or placenta detachment (decollement) Fetal distress The presence of IUGR or macrosomal infant (embryo weighing more than 4000 gr) The presence of underlying illness, such as diabetes or pre-pregnancy or pre-pregnancy hypertension History of cervix trauma Hyoscine susceptibility History of cervical or uterine surgery Using narcotic drugs or analgesics The presence of glaucoma The presence of cardiovascular disease or tachycardia more than 100 beats per minute

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
A 10-by-10 table, which is randomly generated by the computer and contains numbers from 1 to 100, is used. Selecting a sample starts at the first cell from top and left of the table and goes left to right and up to down. Odds numbers are assigned to the control group and even numbers are assigned to the Hyoscine group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Next to Taleghani hospital, Shahid Arabi Ave, Yemen St., Chamran highway

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2018-09-02, 1397/06/11

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.344

Health conditions studied

1

Description of health condition studied

Pregnancy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Cervix status

Timepoint

At the time of entering the design, 24 hours later, and then every 72 hours until delivery and at the time of delivery

Method of measurement

The Bishop Score gives points to 5 measurements of the pelvic examination dilation, effacement of the cervix, station of the fetus, consistency of the cervix, and position of the cervix and its range is 0 to 13.

Secondary outcomes

1

Description

Gestational age at delivery time

Timepoint

At delivery time

Method of measurement

Ask the patient

2

Description

Delivery type
Timepoint
At delivery
Method of measurement
Normal vaginal delivery (NVD), Cesarean section (C/S)

Intervention groups

1

Description
Intervention group: taking oral hyoscine 10 mg twice daily for one week and then once a day in the second week since entering the study (39-40 weeks)

Category
Treatment - Drugs

2

Description
Control group: Expected Treatment

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdieh Hospital
Full name of responsible person
Dr Zahra Naeigi
Street address
Mahdieh Hospital, Shoosh Sq.
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Ali Ziaee
Street address
Next to Taleghani Hospital, Shahid Arabi St., Yemen St., Chamran Highway

City
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1985717443
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msp@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zahra Naeiji
Position
Assitant professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No need for publication

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Naeiji

Position

Assitant professor

Latest degree

Specialist

Other areas of specialty/work