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 Mahdieh 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 rage 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Ali Ziayee

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Next to Taleghani Hospital, Shahid Arabi St., Yemen St., Chamran Highway

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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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Shahid Beheshti University of Medical Sciences

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Latest degree
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Person responsible for updating data

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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