

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the efficacy of hyoscine on dilation of the cervix before hysteroscopy: an open-labeled randomized control trial

Protocol summary

Study aim

Evaluation the efficacy of hyoscine on cervical dilation before hysteroscopy

Design

Randomized control open labeled trial of 100 patients based on random numbers table

Settings and conduct

This study will done among women who referred to Imam Hossein hospital and volunteer to participate in the study and are eligible to enter the study. First, the amount of cervical dilatation is evaluated using bogie number 4. Women who bogie number 4 does not pass through their cervix are divided into two groups of 42 people using a random number table. And 2 hours before the hysteroscopy operation, two hyoscine tablets (10 mg, manufactured by Porsina Pharmaceutical Company) are given to each patient intravaginally, and no intervention is done for the second group (control group). Then, on the day of the surgery, before the start of the surgery, the amount of cervical dilatation of both groups is re-evaluated using bogie number 4.

Participants/Inclusion and exclusion criteria

inclusion criteria: Patient's willing Menopausal women who are planned for hysteroscopy and dilator number 4 does not pass from cervix Negative past cervical surgery Negative allergy history about Hyoscine Negative past medical history about cancers, obstructive bowel disease and cardiopulmonary disease exclusion criteria: Patient's non satisfaction allergy to hyoscine

Intervention groups

intervention group is a candidate to receive vaginal hyoscine tablets. 2 hours before the hysteroscopy procedure, two hyoscine tablets (10 mg, manufactured by Porsina Pharmaceutical Company) are given to each patient intravaginally.

Main outcome variables

cervical dilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220822055772N1**

Registration date: **2023-04-03, 1402/01/14**

Registration timing: **prospective**

Last update: **2023-04-03, 1402/01/14**

Update count: **0**

Registration date

2023-04-03, 1402/01/14

Registrant information

Name

Hanieh Najafiarab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7758 2543

Email address

h_najafi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of hyoscine on dilation of the cervix before hysteroscopy: an open-labeled randomized control trial	
Public title	efficacy of hyoscine on dilation of the cervix
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Patient's willing to participate in study Menopausal women who are planed for hysteroscopy and dilator number 4 does not pass from cervix Negative past cervical surgery Negative allergy history about Hyoscine Negative past medical history about cancers, obstructive bowel disease and cardiopulmonary disease
Exclusion criteria:	not willing to participate in study Sensitivity to hyoscine
Age	No age limit
Gender	Female
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 84
Randomization (investigator's opinion)	Randomized
Randomization description	The randomization method is a simple randomization that is done in the form of individual random units. The tool used to do this is a random numbers table. The method of constructing a random sequence is that first the researcher selects one of the numbers with his eyes closed and then moves in the right direction. Odd numbers are considered for intervention and even numbers are for control. Random concealment is also performed using sequentially numbered sealed opaque envelopes (SNOSE).
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committees of School of Medicine - Shahid Beheshti University of Medical Sciences
Street address	School of medicine of Shahid Beheshti University of medical sciences, Koodakyar Ave., Daneshjoo Blvd., Yaman St., Chamran highway
City	Tehran
Province	Tehran
Postal code	1985717443
Approval date	2023-03-11, 1401/12/20
Ethics committee reference number	IR.SBMU.MSP.REC.1401.660
Health conditions studied	
<u>1</u>	
Description of health condition studied	Menopausal women
ICD-10 code	N95.9
ICD-10 code description	Unspecified menopausal and perimenopausal disorder
Primary outcomes	
<u>1</u>	
Description	cervical dilation
Timepoint	2 hours after medication
Method of measurement	bogie number 4
Secondary outcomes	
<u>1</u>	
Description	hyoscine side effect
Timepoint	after operation
Method of measurement	physician submission
Intervention groups	
<u>1</u>	
Description	Intervention group: The intervention group is candidate to receive hyosine vaginal tablets. 2 hours before the hysteroscopy procedure, two hyoscine tablets (10 mg, manufactured by Porsina Pharmaceutical Company) are given to each patient intravaginally.
Category	Treatment - Drugs

2

Description

Control group: There is no intervention for the control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein Hospital

Full name of responsible person

Hanieh Najafiarab

Street address

Imam Hossein Square, Shahid Madani Street, Tehran Province, Tehran

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 3000

Email

haniye.najafiarab@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, No. 2, Arabi St., Yemen St., Chamran Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2243 9780

Email

Mpajouhesh@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

Hanieh Najafiarab

Position

Research Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Preventative Gynecology Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7758 2543

Email

Haniye.najafiarab@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hanieh Najafiarab

Position

Research Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Preventative Gynecology Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7758 2543

Email

Haniye.najafiarab@gmail.com

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hanieh Najafiarab

Position

Research Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Preventative Gynecology Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7758 2543

Email

Haniye.najafiarab@gmail.com

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

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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