

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Assessing the priming effect of Hyoscine instillation on the cervix of married women aged 20-70.

#### Protocol summary

##### Study aim

Assessing the priming effect of Hyoscine instillation on the unripe cervix of the nonpregnant women

##### Design

In this research, 30 eligible women who are candidates for intrauterine procedure and have closed cervix in primary examination are chosen and the intervention is done without randomization and control group.

##### Settings and conduct

Among the office patients, women who are candidate for intrauterine procedure and have a stenotic cervix are chosen and the researcher writes the information related to their primary examination of their cervix. Then she instills their cervix by 20 mg of hyoscin and after 10 minutes she measures their cervix dilatation with a maximum size dilator device which passes through the cervix hole.

##### Participants/Inclusion and exclusion criteria

Patients who are candidates of intrauterine procedure while having closed cervix; people who want to insert IUD for contraception but have a closed cervix are included to the study and people who have heart disease; people who take sympathetic stimulating medications; patients with hyperthyroidism; women who are allergic to Hyoscine are not included.

##### Intervention groups

patients, who are candidates of intrauterine procedure and have a closed cervix in their primary examination, are chosen and before the procedure, 20 mg of Hyoscine solution is poured on their cervix ostium and the size of cervical os reassessed after 10 minutes.

##### Main outcome variables

uterine cervix opening size

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130119012190N6**

Registration date: **2018-01-26, 1396/11/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-01-26, 1396/11/06**

Update count: **0**

##### Registration date

2018-01-26, 1396/11/06

##### Registrant information

###### Name

Shiva Hadadian

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 23871

###### Email address

shivahadadian@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-12-21, 1396/09/30

##### Expected recruitment end date

2018-04-03, 1397/01/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessing the priming effect of Hyoscine instillation on the cervix of married women aged 20-70.

##### Public title

Priming of the uterine cervix by Hyoscine instillation

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Married women who are candidate for intrauterine procedure having closed cervix in primary examination  
**Exclusion criteria:**  
Heart disease Taking anticholinergic drugs Allergy to Hyoscin Hyperthyroidism

**Age**  
From **20 years** old to **70 years** old

**Gender**  
Female

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Ethical Committee of Shahid Beheshti University of Medical Science

**Street address**

Next to Ayatollah Taleghani Hospital, Yaman Street, Evin, Shahid Chamran High way, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

198396-3113

**Approval date**

2017-11-25, 1396/09/04

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1396.623

## Health conditions studied

### 1

#### Description of health condition studied

closed cervix of the uterine

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

uterine cervix opening diameter

**Timepoint**

At the beginning of the study and ten minutes later.

**Method of measurement**

Dilator with maximum size

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Non pregnant women who are candidate of intrauterine procedure and they have a closed uterine cervix in examination are instilled in the cervix by 20 mg of Hyoscin, produced by Toliddaru company, which is an anticholinergic drug with anti spasm effect.

**Category**

Other

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Gharazi hospital

**Full name of responsible person**

Shiva Hadadian

**Street address**

Gharazi hospital, Shafa St., Malek Ashtar Blvd.

**City**

Sirjan

**Province**

Kerman

**Postal code**

7817831151

**Phone**

+98 34 4142 2200

**Email**

shivahadadian@yahoo.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**

Next to Ayatollah Taleghani hospital, Yaman street,  
Shahid Chamran highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Phone**

+98 21 23871

**Email**

zarghi@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**

Dr Shiva Hadadian

**Position**

gynecologist and obstetrician

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

No.4, Ramezani St., Poonak Sq., Tehran

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Tehran

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**Postal code**

1469653573

**Phone**

+98 21 4447 6473

**Fax****Email**

shivahadadian@yahoo.com

**Web page address**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Shiva Hadadian

**Position**

gynecologist and obstetrician

**Latest degree**

Specialist

**Other areas of specialty/work**

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### Person responsible for updating data

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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gynecologist and obstetrician

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## Sharing plan

### **Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

### **Study Protocol**

Yes - There is a plan to make this available

### **Statistical Analysis Plan**

Yes - There is a plan to make this available

### **Informed Consent Form**

Yes - There is a plan to make this available

### **Clinical Study Report**

Yes - There is a plan to make this available

### **Analytic Code**

Not applicable

### **Data Dictionary**

Not applicable

### **Title and more details about the data/document**

All data related to participants of the study are shareable

after hiding their identities. Also protocol of study, study results, informed consent and statistical analysis plan are shareable.

### **When the data will become available and for how long**

one month after announcing the results of study

### **To whom data/document is available**

Academic people

### **Under which criteria data/document could be used**

doing drug researches

### **From where data/document is obtainable**

shivahadadian@yahoo.com Shiva Hadadian

### **What processes are involved for a request to access data/document**

After expressing the purpose of needing the data via email and sending a letter showing that they are used for scientific purposes, the data would be sent in one month.

### **Comments**