

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A comparative study of vaginal hyoscine butyl bromide and misoprostol on cervical ripening for gynecological intrauterine procedures

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

A comparative study of vaginal hyoscine butyl bromide and misoprostol on cervical ripening for gynecological intrauterine procedures

Last update: **2021-05-25, 1400/03/04**

Update count: **0**

Registration date

2021-05-25, 1400/03/04

Design

The clinical trial, with parallel groups, randomized, Double blind, single-center trial, sample size 50 people. Patients are allocated randomly with simple sequential allocation in one of the two study groups by help of sealed envelope and receive the intervention of the same group. Drug packaging is coded. So that the evaluators and patients are unaware of the drug content packaging and intervention that they receive.

Registrant information

Name

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Name of organization / entity

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Settings and conduct

Amir Al-Momenin Hospital. Hyoscine butylbromide oral tablet (40 mg dose) and misoprostol (200µg) is inserted vaginally into the posterior cervical region 2 hours before the intervention.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 55 years; Before menopause.

Exclusion criteria: Pregnancy; History of more than 3 deliveries; Anatomic abnormalities in the genital tract; Infection or wound visible in the cervix or vagina.

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Intervention group: Hyoscine butylbromide oral tablet (40 mg dose) is inserted vaginally into the posterior cervical region 2 hours before the intervention. Control group: Misoprostol (200µg) is inserted vaginally into the posterior cervical region 2 hours before the intervention.

Main outcome variables

Cervical diameter; The amount of pain; Bleeding rate.

Scientific title

A comparative study of vaginal hyoscine butyl bromide and misoprostol on cervical ripening for gynecological intrauterine procedures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N68**

Registration date: **2021-05-25, 1400/03/04**

Public title

A comparative study of vaginal hyoscine butyl bromide

and misoprostol on cervical ripening for gynecological intrauterine procedures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 55 years Before menopause

Exclusion criteria:

Pregnancy History of more than 3 deliveries Anatomic abnormalities in the genital tract Infection or wound visible in the cervix or vagina

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are allocated randomly with simple sequential allocation in one of the two study groups by help of sealed envelope and receive the intervention of the same group. The unit of randomization is patient. Sealed envelopes are delivered to expert. With each patient's visit, one of the envelopes is randomly selected by the patients and determines the study group. The stratification approach is not used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drug packaging is coded. So that the evaluators and patients are unaware of the drug content packaging and intervention that they receive.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2021-02-23, 1399/12/05

Ethics committee reference number

IR.SEMUMS.REC.1399.324

Health conditions studied

1

Description of health condition studied

Intrauterine interventions

ICD-10 code

Z01.4

ICD-10 code description

Encounter for gynecological examination

Primary outcomes

1

Description

Cervical diameter

Timepoint

Before and after the intervention

Method of measurement

The largest size of Hegar dilator that can be inserted without resistance and easily.

2

Description

The amount of pain

Timepoint

Before and after the intervention

Method of measurement

Visual analogue scale for pain (0 to10)

3

Description

Bleeding rate

Timepoint

Before and after the intervention

Method of measurement

Cylindrical (cc)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Hyoscine butylbromide oral tablet

(40 mg dose) is inserted vaginally into the posterior cervical region 2 hours before the intervention.

Category

Diagnosis

2

Description

Control group: Misoprostol (200µg) is inserted vaginally into the posterior cervical region 2 hours before the intervention.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-Momenin Hospital

Full name of responsible person

Shahrzad Aghaamoo

Street address

Amir Al-Momenin Hospital, Mostafa Khomeini Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Shahrzad Aghaamoo

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Full name of responsible person

Shahrzad Aghaamoo

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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Mahshid Khakzad

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Resident

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Specialist

Other areas of specialty/work

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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

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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available