

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Efficacy of sublingual misoprostol with sublingual misoprostol with laminaria on cervical dilation in the abortion rate from 4 to 14 weeks

Protocol summary

Summary

Objectives: Find a way to faster cervical ripening. Design: interventional. Setting and conduct: The two groups were matched in the first group of sublingual misoprostol 400µg 4 hours before procedure and the intervention group to receive cervical laminaria plus 200µg sublingual misoprostol 4 hours before procedure. Inclusion criteria: 18 to 35 years; gestational age less than 14 weeks; closed cervix; ultrasound consecutive Blighted Ovum or Missed Abortion or the termination of pregnancy to order a forensic document. Exclusion criteria: medical conditions such as diabetes or high blood pressure or heart disease; surgery on the cervical area of the cervix; women who take certain medications or an underlying allergy; Women who have vaginal bleeding at presentation; women with a BMI of less than 20 or more than 25; more than 2 previous cesarean section; uterine anomalies.

Intervention: Misoprostol 400µg 4 hours before procedure in the control group and misoprostol 200µg plus laminaria in the intervention group. The outcome of the investigation's achieving the desired cervical dilation or spontaneous expulsion of pregnancy products, pain intensity during waiting period, adverse effects of the ripening methods including nausea/vomiting, diarrhea, flushing and fever, post abortive infection and finally the patients' satisfaction at discharge.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070711020N4**
Registration date: **2015-07-24, 1394/05/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-24, 1394/05/02

Registrant information

Name

Maryam Khoshideh

Name of organization / entity

Tehran University of Medical Sciences, Arash Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 0909

Email address

khooshide@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice President of Medical Sciences, Tehran University of Medical Sciences

Expected recruitment start date

2015-07-24, 1394/05/02

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of sublingual misoprostol with sublingual misoprostol with laminaria on cervical dilation in the abortion rate from 4 to 14 weeks

Public title

Improving the effectiveness of misoprostol cervical ripening with laminaria

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18 to 35 years ;gestational age less than 14 weeks;closed cervix;ultrasound consecutive Blighted Ovum or Missed Abortion or the termination of pregnancy to order a forensic document. Exclusion criteria: medical conditions such as diabetes or high blood pressure or heart disease; surgery on the cervical area of the convention; women who take certain medications or an underlying allergy;Women who have vaginal bleeding at presentation ; women with a BMI of less than 20 or more than 25 ; more than 2 previous cesarean section; uterine anomalies .

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

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 committe of Tehran University of Medical Science

Street address

Tehran University of Medical Science, Qods street

City

Tehran

Postal code

Approval date

2015-04-08, 1394/01/19

Ethics committee reference number

9111290040-144511

Health conditions studied

1

Description of health condition studied

Abortion

ICD-10 code

o04

ICD-10 code description

termination of pregnancy: legal therapeutic therapeutic abortion

Primary outcomes

1

Description

400µg sublingual misoprostol for cervical ripening

Timepoint

Every 4 hours

Method of measurement

≥Hegar7

2

Description

cervical ripening with:cervical laminaria plus 200µg sublingual misoprostol

Timepoint

Every 4 hours

Method of measurement

≥Hegar7

Secondary outcomes

1

Description

Symptoms of allergy to laminaria

Timepoint

every tow hours up to cervix prparation

Method of measurement

based on fever and Itching existance

2

Description

fever

Timepoint

every 2 hours up to preparation ofcervix

Method of measurement

Medical thermometer

Intervention groups

1

Description

Intervention group:receive cervical laminaria plus 200µg sublingual misoprostol 4 hours before procedure.

Category

Treatment - Other

2

Description

procedure Control group: sublingual misoprostol 400µg 4

hours before procedure

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women 's Hospital

Full name of responsible person

Dr Maryam Khooshide

Street address

162 Alley, Rashid Aven,Resalat Hay way

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran University of Medical Sciences , Deputy of Research

Full name of responsible person

Dr. Akbar Fotohi

Street address

Qods St, Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Tehran University of Medical Sciences , Deputy of Research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Maryam Khooshide

Position

Associate professor

Other areas of specialty/work

Street address

Arash Women 's Hospital 162 Alley, Rashid Aven,Resalat Hay way

City

Tehran

Postal code

Phone

+90 217 788 32 88

Fax

Email

khooshide@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Dr Maryam Khooshide

Position

Associate professor

Other areas of specialty/work

Street address

Arash Women 's Hospital 162 Alley, Rashid Aven,Resalat Hay way

City

Tehran

Postal code

Phone

+98 21 7788 3288

Fax

Email

khooshide@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Nassim Yarmohammadi

Position

Gynecology Resident

Other areas of specialty/work

Street address

Arash Women 's Hospital 162 Alley, Rashid Aven,Resalat Hay way

City

Tehran

Postal code

Phone

00

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty