

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Glyceryl Trinitrate Versus Misoprostol for Cervical Ripening in Diagnostic Curettage, A single blind clinical trial study

Protocol summary

Study aim

Determination and comparison of misoprostol and trinitrate glycerin (TNG) effects for cervix preparation for diagnostic curettage at Shahid Sayyad Shirazi Medical Center

Design

. After obtaining a detailed history, a complete physical examination, and checking CBC, BG and RH, as well as the cervical dilatation level from patients, will be determined before the drug administration. Subjects will then be randomly assigned to either group A (TNG recipients) and group B (misoprostol recipients). Group A will receive three doses of vaginal TNG (manufactured by Zahravi Pharmaceutical Company) at 1200 micrograms (every 3 hours). Group B will also receive 200 micrograms of vaginal misoprostol (200 micrograms misoglandin tablet, Samisaz Pharmacy [Iran]). After 6 hours, both groups will be transferred to the operating room for the curettage. In the operating room, the cervical patency will be measured in millimeters using dilators.

Settings and conduct

A randomized single blind clinical trial study was performed in Golestan province, Gorgan, Sayad Shirazi Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Age > 35 • lack of sensitivity to trinitrate glycerin and misoprostol • Absence of cardiovascular disease • Hemoglobin level > 10 g / l • Closure of the cervix • Consent to participate in the study
Exclusion criteria: • Abnormalities in patient's test results including coagulation and CBC disorders • Special medical conditions such as severe anemia, coagulation disorders, glaucoma, and bronchial asthma PID presence (endometritis , salpingitis ...) and vaginal infection

Intervention groups

All women referred to the clinic and maternity ward of Sayyed Shirazi Hospital with AUB complaint (abnormal bleeding) and candidates for diagnostic curettage during

2020

Main outcome variables

TNG and misoprostol effects on cervical ripening before diagnostic curettage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201105049276N1**

Registration date: **2020-11-10, 1399/08/20**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-10, 1399/08/20**

Update count: **0**

Registration date

2020-11-10, 1399/08/20

Registrant information

Name

Azam Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3226 1150

Email address

dr.aminichabok@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-14, 1399/07/23

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Glyceryl Trinitrate Versus Misoprostol for Cervical Ripening in Diagnostic Curettage, A single blind clinical trial study

Public title

Comparison of Glyceryl Trinitrate Versus Misoprostol for Cervical Ripening in Diagnostic Curettage

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Age > 35 years No allergy history to Glyceryl Trinitrate and Misoprostol Hb > 10 g/dl Closure of the cervix Consent to participate in the study

Exclusion criteria:

Abnormalities in patient's test results including coagulation and CBC disorders Special medical conditions such as severe anemia, coagulation disorders, glaucoma, and bronchial asthma PID presence (endometritis , salpingitis , ..) and vaginal infection

Age

From **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Care provider

Sample size

Target sample size: **168**

Randomization (investigator's opinion)

Randomized

Randomization description

We use the block randomization method to randomize subjects into groups that result in equal sample sizes. We use the block size 4. From the following blocks, first select 1 by accident and divide the samples into two groups according to the order and fill the blocks A for intervention and B for placebo B A B A 2) B B A A 1) B A A B 4) A B B A 3) A A B B 6) A B A B 5)

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is single-blind and the medical examiner resident and medication provider would not know about the type of treatment. After obtaining a detailed history, a complete physical examination, and checking CBC, BG and RH, as well as the cervical dilatation level from patients, will be determined before the drug administration.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Golestan University of Medical Sciences

Street address

Golestan University of Medical Sciences, Gorgan, Shastkola road, Philosophical Higher Education Complex

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2020-10-13, 1399/07/22

Ethics committee reference number

IR.GOUMS.REC.1399.224

Health conditions studied**1****Description of health condition studied**

Cervical Ripening

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Ease of cervical ripening

Timepoint

6 Hours after administration

Method of measurement

Hegar Dilator size (mm)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: TNG recipients will receive three doses of vaginal TNG (manufactured by Zahravi Pharmaceutical Company) at 1200 micrograms (every 3 hours)

Category

Treatment - Drugs

2

Description

Intervention group: misoprostol recipients receive 200 micrograms of vaginal misoprostol (200 micrograms misoglandin tablet, Samisaz Pharmacy [Iran])

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sayyad Shirazi Hospital

Full name of responsible person

Dr Afsane Tanabande

Street address

Philosophical Higher Education Complex, Shast Kola Road, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3220 2565

Email

dr.tabande@goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Honarvar

Street address

Philosophical Higher Education, Shast Kola Road, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3245 1660

Fax

+98 17 3245 1657

Email

info@goums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

En Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Dr Azam Amini

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Golestan University of Medical Sciences, Shast Kola Road, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3220 2565

Email

pfarjad13@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr Azam Amini

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Golestan University of Medical Sciences, Shast Kola Road, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3220 2565

Email

pfarjad13@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr Azam Amini

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Golestan University of Medical Sciences, Shast Kola
Road, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3220 2565

Email

pfarjad13@gmail.com

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

It will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Use of data to complete the research process on the effects of using misoprostol and glycerin trinitrate (TNG) to cervix ripening for diagnostic curettage

From where data/document is obtainable

Contact the author of the article responsible for the research project data.

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

Contact the author of the article responsible for the research project data. Specify the type of results requested.

Comments