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)

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+98 17 3226 1150

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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
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4934174515
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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
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Philosophical Higher Education, Shast Kola Road, Gorgan
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Fax
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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
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Person responsible for updating data

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Full name of responsible person

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Latest degree

Medical doctor

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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

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