Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Compare misoprostol and isosorbide mononitrate to soften the servix for infertile women undergonig histroscopy

Protocol summary

Study aim
Compare misoprostol and isosorbide mononitrate to soften the servix in infertile women undergoing hysteroscopy

Design
In this study, 56 infertile nulliparous women need cervical softening for undergoing surgical hysteroscopy were participated. Patients were randomly divided into two groups and the first group received 25 µg misoprostol (vaginal every 4 hours to 4 doses) and the second group received 40 mg of isosorbide mononitrate (vaginal every 6 hours to 2 doses).

Settings and conduct
Samples are selected among available patients in the hospital, which are entered into the study sequentially

Participants/Inclusion and exclusion criteria
Infertile women undergoing hysteroscopy

Intervention groups
Patients entering the study were randomly divided into two groups. The first group received misoprostol at 25 micrograms (vaginal every 4 hours to 4 doses) and the second group received isosorbide mononitrate 40 mg (vaginal every 6 hours to two doses).

Main outcome variables
Headache; abdominal pain; nausea and vomiting; heart rate; respiratory rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180826040879N1**
Registration date: **2019-03-09, 1397/12/18**
Registration timing: **retrospective**

Last update: **2019-03-09, 1397/12/18**
Update count: **0**

Registration date
2019-03-09, 1397/12/18

Registrant information

Name
Yasin Ganjali

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-05-14, 1396/02/24

Expected recruitment end date
2017-11-23, 1396/09/02

Actual recruitment start date
2017-05-14, 1396/02/24

Actual recruitment end date
2018-11-23, 1397/09/02

Trial completion date
2019-02-20, 1397/12/01

Scientific title
Compare misoprostol and isosorbide mononitrate to soften the servix for infertile women undergonig histroscopy

Public title
Compare misoprostol and isosorbide mononitrate to soften the servix for infertile women undergonig histroscopy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

infertile wemen undergoing histroscopy

Exclusion criteria:

This study is conducted on infertile women undergoing hysteroscopic surgery

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **56**

Actual sample size reached: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple and individual random sampling was done using a random number table. According to the size of the community which was 56 people, we chose a random start point to select the units. Finally, we started the selection from this point and considered each number smaller than or equal to 56 as the sample.Even numbers were assigned to misopristol group and odd numbers were assigned to isosorbide group.

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

Zabol University of Medical Sciences Ethics Committee

Street address

Zabol - Shahid Rajaee Street - Educational Complex

City

Zabol

Province

Sistan-va-Balouchestan

Postal code

9861615881

Approval date

2018-06-24, 1397/04/03

Ethics committee reference number

IR.ZBMU.REC.1397.059

Health conditions studied

1

Description of health condition studied

Comparison of the effect of misoprostol and isosorbide mononitrate on cervix

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Study of headache after taking misoprostol and isosorbide mononitrate on cervix

Timepoint

Headache in the beginning of the study after taking Misoprostol and isosorbide mononitrate on the cervix

Method of measurement

Asking questions from the patient himself

2

Description

Study of nausea and vomiting after taking misoprostol and isosorbide mononitrate on cervix

Timepoint

Nausea and vomiting at the beginning of the study following the use of Mizo, Prostol and Isosorbide Mononitrate on the cervix

Method of measurement

Asking questions from the patient himself

3

Description

Evaluation of abdominal pain after taking misoprostol and isosorbide mononitrate on the cervix

Timepoint

Abdominal painat the beginning of the study following the use of Mizo, Prostol and Isosorbide Mononitrate on the cervix

Method of measurement

Asking questions from the patient himself

4

Description

Evaluation of cervical dilatation after taking misoprostol and isosorbide mononitrate

Timepoint

Study of cervical dilatation rate at the beginning of study after misoprostol and isosorbide mononitrate

Method of measurement

Respectively, using small to large bogies

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group received 25 µg misoprostol (vaginal every 4 hours to 4 doses)
Category
Treatment - Drugs

2

Description
Control group: 60 mg isosorbine mononitrate suppository every 6 hours until two doses
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Zabol Amir Al Momenin hospital
Full name of responsible person
Zahra Shahraki
Street address
Zabol - Shahid Rajaee Street - Educational Complex
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zabol University of Medical Sciences
Full name of responsible person
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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
Zabol 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
Zabol University of Medical Sciences
Full name of responsible person
Zahra Shahraki
Position
Associate professor
Latest degree
Subspecialist
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Gynecology and Obstetrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more info
Study Protocol
No - There is not 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