Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing effects of crocin and misoprostrol consumption on cervical ripening in women undergoing operative hysteroscopy: a randomised clinical trial

Protocol summary

Study aim

The purpose of this study is to evaluate the effect of oral administration of crocin tablet on cervical readiness in women who are candidates for hysteroscopy.

Design

A two-blind randomized clinical trial with a parallel group design of 50 patients, enrolled between October 2018 and October 2019

Settings and conduct

The setting of the study is the Gynecology ward and the operating room of Rasoul-e-Akram Hospital. First, pelvic exam is done for each patient candidate for hysteroscopy. Then a concealed enclosed envelope is given to the patient by a third person not invloved in the study which includes 4 tablets to ingest orally two of them the evening and two of them the night before operation. The patients and the surgeon are blind to the tablets.The morning of surgery repeat exam is done. Then entering dilators from the least diameter to the maximum diameter passed from cervical canal without resistance is performed. All the information is documented in the questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All women who are candidates for operative hysteroscopy, Having written informed consent for using the cervical ripening agent, Having no allergy to saffron or prostaglandins , Exclusion criteria: Suffering from active hepatic, renal, hematologic and or cardiologic disorder, Suffering from approved malignancy of the genital tract , Approved cervical insufficiency

Intervention groups

Intervention group: Two oral crocin 15 mg tablets (Krocina tablet produced by Sami Saz Co., Mashhad) will be prescribed to patients at 6 pm and two at 12 midnight before the surgery. Control group: Two misoprostol tablets (CYTOTEC 100 µg, Pfizer Co.) will be prescribed to patients at 6 pm and two at 12 midnight before the surgery.

Main outcome variables

The extent of cervical canal dilatation before the onset of hysteroscopy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150909023949N9**
Registration date: **2018-11-24, 1397/09/03**
Registration timing: **prospective**

Last update: **2018-11-24, 1397/09/03**
Update count: **0**

Registration date

2018-11-24, 1397/09/03

Registrant information

Name

Mansoureh Vahdat

Name of organization / entity

Iran University of medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-11-06, 1398/08/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing effects of crocin and misoprostrol consumption on cervical ripening in women undergoing operative hysteroscopy: a randomised clinical trial

Public title
Comparing crocin and misoprostol effects on cervical ripening
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All women who are scheduled for operative hysteroscopy No history of allergy to saffron or prostaglandins Having written informed consent
Exclusion criteria:
Suffering from active hepatic, renal, hematologic or cardiologic disorder Approved known malignancy of genital tract Approved cervical insufficiency
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 50 women who are candidates for hysteroscopy will be divided into two groups of control and case (25 each).Using a table of random numbers, a number from 1 to 50 is attributed to each patient. Crocin tablets will be given to odd numbers as the case group and misoprostol tablets will be given to even numbers as the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients receiving the tablets and the surgeon performing the hysteroscopy are blind to the study. Tablets put in enclosed opaque envelopes will be numbered A or B and will be given to patients by a third person unaware of the study.
Placebo
Not used
Assignment
Parallel
Other design features
Iran is considered one of the main countries which export saffron, therefore, any study highlighting the value of this herb in medicine could be of significant importance in improving the economic conditions of the society. This would be the first study which assess the effects of one of the main constituents of saffron on cervical softening which could have desirable outcomes in the minimally invasive surgical procedures used in the gynecology field

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Rasoul-e-Akram Hospital, Maziar Mansouri Street, Sattarkhan Street
City
Tehran
Province
Tehran
Postal code
1445613131
Approval date
2018-08-26, 1397/06/04
Ethics committee reference number
IR.IUMS.REC.1397.232

Health conditions studied

1

Description of health condition studied
Uterine polyp
ICD-10 code
N84.0
ICD-10 code description
Polyp of corpus uteri

2

Description of health condition studied
endometrial hyperplasia
ICD-10 code
N85.0
ICD-10 code description
Endometrial glandular hyperplasia

3

Description of health condition studied
submucosal fibroid
ICD-10 code
D25.0
ICD-10 code description
Submucous leiomyoma of uterus

4

Description of health condition studied
Abnormal uterine bleeding
ICD-10 code
ICD-10 code description

5

Description of health condition studied
excessive bleeding in the premenopausal period
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Size of the largest dilator passed from cervical canal without resistance
Timepoint
After the induction of the anesthesia and before entering the hysteroscope in the operating room
Method of measurement
examination performed by the surgeon- Using standard dilators in the operating room

Secondary outcomes

1

Description
The extent of cervical tissue softening
Timepoint
After induction of anesthesia and before entering the hysteroscope in the operating room
Method of measurement
examination by the surgeon in the operating room

2

Description
The length of time of the procedure till entering the uterine cavity
Timepoint
After induction of anesthesia in the operating room
Method of measurement
Using chronometer by the surgeon's assistant

Intervention groups

1

Description
Intervention group: Two crocin 15 mg tablets (Sami Saz Co. mashhad) are given to patients at 6 pm and 12 midnight before surgery.
Category
Treatment - Drugs

2

Description
Control group: Two misoprostol 100 microgram (CYTOTEC ,Pfizer Co.) tablets are given at 6 pm and 12 midnight before surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul-e-Akram Hospital
Full name of responsible person
Mansoureh Gorginzadeh
Street address
Rasoul-e-Akram Hospital, Mazar-i-Mansouri St., Sattarkhan Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Kazem Malakouti
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Iran University of Medical Science, Hemmat Highway, Tehran
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1449614535
Phone
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Email
malakoutik@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Mansoureh Vahdat

Position
associate professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
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Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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Fellowship of minimally invasive surgery

Latest degree
Specialist

Other areas of specialty/work
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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
There is no more information available.

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