

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparing effects of crocin and misoprostol 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 involved 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)

##### Phone

+98 21 6650 9283

##### Email address

vahdat.m@iums.ac.ir

##### 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 misoprostol 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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Tehran

##### Province

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1445613131

##### Phone

+98 21 6435 2562

##### Email

inf.erc@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Kazem Malakouti

##### Street address

Iran University of Medical Science, Hemmat Highway, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Phone

+98 21 86701

##### 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

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

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**Email**

vahdat.m@iums.ac.ir

**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 updating data**

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**Full name of responsible person**

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**Position**

Fellowship of minimally invasive surgery

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Person responsible for scientific inquiries**

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**Name of organization / entity**

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**Full name of responsible person**

Mansoureh Vahdat

**Position**

associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Rasoul-e-Akram Hospital, Niayesh St., Sattarkhan Street

**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