# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## The effect of oral Crocus Sativus (Saffron) tablet on cervical ripening in term pregnant women: a randomized controlled trial

## Protocol summary


**Summary**

The aim of this study is to determine the effect of Saffron oral tablet on cervical ripening in women with gestational age of 39-41 weeks. In this triple blind clinical trial, 50 eligible pregnant women will be allocated into two, Saffron or placebo, groups using block randomization stratified by parity with allocation ratio 1:1 and block sizes of 4 and 6 (determined with a computerized program). A person not involved in sampling and data collection will put the tablets into sequentially numbered sealed opaque envelopes to conceal allocation sequence. After collecting baseline characteristics and determining the Bishop score, every participant will get an envelope containing three 250 mg Saffron or placebo tablets and will be asked to take orally one pill every 8 hours. Subjects will be followed every 3-6 hours in terms of pain, bleeding, rupture of membranes and decreased fetal movements over phone for 24 hours. The subjects will refer to the hospital 10-12 h and 20-24 h after the starting to take the pills and also when occurring any of the events and the Bishop score and other outcomes will be examined. Non-stress test will be done at 24 hours after starting the intervention for any subject not admitted for delivery in this period. If it was reactive, she will leave the hospital and will be followed up in terms of outcomes of interest. Data will be analyzed using independent sample T-test, ANCOVA and chi-square tests.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201212233706N19**
Registration date: **2013-03-17, 1391/12/27**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2013-03-17, 1391/12/27

**Registrant information**


**Name**

Sakineh Mohammad-Alizadeh-Charandabi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 41 3477 2699

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**Recruitment status**

**Recruitment complete**


**Funding source**

Tabriz University of Medical Sciences


**Expected recruitment start date**

2013-03-27, 1392/01/07

**Expected recruitment end date**

2013-05-22, 1392/03/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of oral Crocus Sativus (Saffron) tablet on cervical ripening in term pregnant women: a randomized controlled trial

**Public title**

The effect of oral Crocus Sativus (Saffron) tablet on cervical ripening in pregnant women with gestational age of 39-41 weeks

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: 1. Women with 1-3 gravidity and gestational age of 39-41 weeks 2. Not starting uterine contractions 3. Willing to deliver in Bonab hospital 4. Secondary and higher educational level 5. Bishop score of four or less 6. Singleton pregnancy 7. Cephalic presentation 8. Intact amniotic sac 9. Reactive non-stress test 10. Estimated fetal weight of 2500 to 4000 grams by ultrasound or examination. Exclusion criteria: 1. History of cryotherapy or cautery of the cervix 2. History of cesarean or having any indication for cesarean section in current pregnancy 3. Diagnosed fetal anomalies 4. Cephalo-Pelvic Disproportion 5. Any known placental problem (placenta previa, placental abruption, placental insufficiency) 6. Maternal infection and systemic chronic diseases, including respiratory diseases, cardio - vascular, endocrine and... 7. Using any of the following drugs by the woman (oral hypoglycemic agents and insulin, anticoagulants such as aspirin and Warfarin ,non steroidal -anti-inflammatory drugs such as ibuprofen and naproxen, herbal drugs and antihypertensives, benzodiazepines such as lorazepam and diazepam, barbiturates such as phenobarbital, narcotics, antidepressant, Alcohol) 8. Not access to telephone line

**Age**

From **18 years** old to **39 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Research deputy, Tabriz University of Medical Sciences

**Street address**

Golgasht street

**City**

Tabriz

**Postal code**

**Approval date**

2013-02-18, 1391/11/30

**Ethics committee reference number**

91219

## Health conditions studied

### 1

**Description of health condition studied**

Cervical ripening

**ICD-10 code**

O62.0

**ICD-10 code description**

Primary inadequate contractions

## Primary outcomes

### 1

**Description**

Bishop score

**Timepoint**

Befor intervention, at the time of onset of uterin contractions, 10-12 and 20-24 hours after intervention or at the time of doing other treatment interventions

**Method of measurement**

The Bishop rating system

## Secondary outcomes

### 1

**Description**

Duration of the first stage of labor

**Timepoint**

After finishing the first stage of labor

**Method of measurement**

Patient record

### 2

**Description**

Interval of onset of uterine active contractions and starting intervention

**Timepoint**

In the 24 hours after starting intervention

**Method of measurement**

Patient and clinician report

### 3

**Description**

Duration of the second stage of labor (in minutes)

**Timepoint**

After finishing the second stage of labor

**Method of measurement**

Observation and physical exam

**4**

**Description**
Need to induce labor
**Timepoint**
Between admission in delivery room and delivery
**Method of measurement**
According to hospital records

**5**

**Description**
Delivery type
**Timepoint**
After delivery
**Method of measurement**
According to hospital records

**6**

**Description**
Vaginal delivery in 24 hours after starting intervention
**Timepoint**
24 hours after intervention
**Method of measurement**
According to hospital records

**7**

**Description**
Amount of hemorrhage
**Timepoint**
The time of admission in delivery room and 12 hours after delivery
**Method of measurement**
Hematocrit assessment

## Intervention groups

**1**

**Description**
Intervention group: Receiving 3 doses of oral 250 mg saffron tablets each 8 hours
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Receiving 3 doses of oral 250 mg placebo tablets each 8 hours
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shohada hospital
**Full name of responsible person**
Sadi Roghaieh
**Street address**
Zavaraq road, opposite of Imam-e-Asr seminary
**City**
Bonab

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Research deputy of Tabriz university of medical sciences
**Full name of responsible person**
Dr. Kazem Shakouri
**Street address**
Golgasht st.
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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**
Research deputy of Tabriz university of medical sciences
**Proportion provided by this source**
100
**Public or private sector**
*empty*
**Domestic or foreign origin**
*empty*
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences
**Full name of responsible person**
Sadi Roghaieh
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## Person responsible for scientific inquiries

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Assistant professor, PhD in Reproductive Health

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## Person responsible for updating data

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Sakineh Mohammad-Alizadeh Charandabi

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Assistant professor, PhD in Reproductive Health

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*

**Study Protocol**
*empty*

**Statistical Analysis Plan**
*empty*

**Informed Consent Form**
*empty*

**Clinical Study Report**
*empty*

**Analytic Code**
*empty*

**Data Dictionary**
*empty*