Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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

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Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3477 2699

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alizades@tbzmed.ac.ir

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.
City
Tabriz
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
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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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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