Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Saffron capsule on cervical ripening, beginning and delivery outcomes in primiparous women

Protocol summary

Summary

The aim of this study is to determine the effect of Saffron oral capsule on cervical ripening in nulliparous women. In this double blind clinical trial, 100 eligible pregnant women referring to Esfahan Zahariey Marzieh hospital, will be allocated into two groups, Saffron or placebo, by using random allocation software for clinical trial. After collecting baseline characteristics and determining the Bishop score, every participant will get a packet containing three Saffron or placebo capsules (250 mg) and will be asked to take one pill every 24 hours orally. The subjects will refer to the hospital 3 days after the start of taking the capsules and also when pain, bleeding, rupture of membranes and decreased fetal movements occurs. Then the Bishop score and other outcomes will be examined. If Bishop score is appropriate (5 or more), patients will be hospitalized. Otherwise, if Non-stress test is reactive, the patient will leave the hospital and will get another packet containing three Saffron or placebo capsules again and will be followed up for next 3 days and will be evaluated in terms of outcomes of interest. Finally, results will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201603243860N24**
Registration date: **2016-12-09, 1395/09/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-12-09, 1395/09/19

Registrant information

Name

Gity Ozgoli

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

gozgoli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-08-21, 1395/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Saffron capsule on cervical ripening, beginning and delivery outcomes in primiparous women

Public title

Evaluation of Saffron capsule on cervical ripening.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: primiparous woman; age between 18 to 35 years; gestational age of 40 weeks or more; singleton pregnancy with cephalic presentation; not starting uterine contraction; Bishop score less than or

equal 4; intact amniotic sac; normal pattern of fetal heart rate; reactive non-stress test; fetal weight between 2500 to 4000; low-risk pregnancy (without known surgical diseases and internal disease or pregnancy complications such as preeclampsia, placental abruption, previa and the absence of known fetal problems); avoiding the use of herbal medicines, chemical or traditional methods for induction of labor in 36 hours before treatment; lack of sex from 24 hours before the beginning till end of the study. Exclusion criteria: Use of oral Saffron; cephalo-pelvic disproportion; using uterine stimulant drugs during the study, such as castor oil; obstetric emergency cases.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The random allocation is done using random numbers table and sealed envelope.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of International Branch of Behesti University of Medical Sciences and Health Servi

Street address
International Branch of Behesti University of Medical Sciences, No.19, Next to the Hemmat bridge, Shahid Abbaspoor St, Vali Asr St(tavanir), Tehran, Iran.

City
Tehran

Postal code
1985717443

Approval date
2016-04-17, 1395/01/29

Ethics committee reference number
IR.SBMU.RAM.REC.1395.53

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
cervical ripeningat

Timepoint
Before the intervention, three days later

Method of measurement
Bishop score table

Secondary outcomes

1

Description
Duration and frequency of uterine contractions per hour

Timepoint
During 3 days after starting intervention

Method of measurement
Observation and physical exam

2

Description
mode of delivery

Timepoint
After intervention

Method of measurement
observation

3

Description
Duration of the first stage of labor (in minutes)

Timepoint
After finishing the first stage of labor

Method of measurement
Patient record

4

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

5

Description
Duration of the third stage of labor (in minutes)
Timepoint
After finishing the third stage of labor
Method of measurement
Observation and physical exam

Intervention groups

1

Description
Intervention group: 3 Saffron oral capsules (250 mg) are prescribed and patients should take one capsule every 24 hours for 3 days. These capsules are produced in Shahid Beheshti pharmacy faculty.
Category
Treatment - Drugs

2

Description
Control group: Placebo capsule containing 250 mg of lactose powder that have been prepared under the supervision of pharmacist. Three oral capsules are prescribed and patients should take one capsule every 24 hours (daily) for 3 days. These capsules are produced in Shahid Beheshti pharmacy faculty.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Zahraye Marzie Charity Hospital
Full name of responsible person
Bahareh Ali-akbar Sichani
Street address
Shahid Mohamad Salehi Alley, Hosein Abad st, Hakim Nezami st, Isfahan.
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr.Mahrokh Dolatian
Street address
School of Nursing and Midwifery, Niayesh Highway, Valiasr St, Tehran, Iran
City
Tehran
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Shahid Beheshti 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
School of Nursing and Midwifery of Shahid Beheshti University of Medical Sciences
Full name of responsible person
Giti Ozgoli
Position
PHD of Midwifery /Superviser
Other areas of specialty/work
Street address
School of Nursing and Midwifery, Niayesh Highway, Valiasr St, Tehran, Iran
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

Contact

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