

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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 Abbaspour 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 /Supervisor

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Niayesh Highway, Valiasr St, Tehran, Iran

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery of Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

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Web page address**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*