Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of saffron capsule on labor anxiety in primiparous women

Protocol summary

Summary

This double-blind clinical trial aims to determine the effect of saffron oral capsule on labor anxiety in primiparous women. 60 pregnant women with a gestational age of 40 weeks or more who are referred to the hospital and Darul-Shafa Hospital of Zahraye Marzieh in Isfahan city were selected by simple sampling method and in the process of random appointment of individuals in groups will use Random allocation software for clinical trial. The drug packs were numbered in two codes, A and B, to 60, containing 3 capsules of saffron or placebo (code-packed). In order to remove the bias in the control group, placebo containing 250 mg of lactose powder and saffron capsules and placebo in terms of appearance, including odor and color were similar.Blinding was performed for two groups of subjects (patients) and researchers. After obtaining the written consent of the eligible individuals, they receive the envelope in the code in which they receive. In each group, at the beginning of the 40th week of gestation, a capsule of saffron or placebo is given in a dose of 250 mg per night to 3 nights. After three days from the beginning of the 40th week, they are admitted based on the routine of the center. The degree of anxiety will be measured in two stages (at the time of entering the study, when admitted to the labor sector). The instruments of this study were demographic and midwifery questionnaires and Spielberger anxiety questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707133860N30**
Registration date: **2017-08-08, 1396/05/17**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-08-08, 1396/05/17

Registrant information

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Shahid Beheshti University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-16, 1396/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of saffron capsule on labor anxiety in primiparous women

Public title

Effect of saffron on labor anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 to 35, first pregnancy; single pregnancy pregnancy; embryonic cephalic presentation; gestational age 40 to 41 weeks or more

based on the first day of the last menstruation and ultrasonography of the first trimester; no uterine contraction; bishop score lower or equal to 4; healthy gestational sac; regular fetal heart rate; normal non-stress test; estimated embryo weighing 2500-4000; a low risk pregnancy (no known signs of internal and surgical diseases, or complications such as preeclampsia and Placental abruption and absence of known embryonic problems); pelvic stenosis; don’t receive any herbal remedy or medication such as misoprostol, prostaglandin, Oxytocin 36 hours before treatment; no sexual intercourse from 24 hours before and up to the end of the study. Exclusion criteria: oral consumption of saffron; uterine contraction; fetal heart rate abnormalities and absence of fetal movement, use of stimulants for uterine contractions during the study; such as castor oil; midwifery requiring emergency procedures, such as intense hemorrhage.

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Pharmacy and Nursing Schools, Midwifery

Street address
School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Valleye Asr street, Tehran, Iran.

City
Tehran

Postal code

Approval date
2016-07-20, 1395/04/30

Ethics committee reference number
IR.SBMU.PHNM.1395.438

Health conditions studied

1

Description of health condition studied
anxiety

ICD-10 code
F41.1

ICD-10 code description
Anxiety that is generalized and persistent but not restricted to, or even strongly predominating in, any particular environmental circumstances (i.e. it is

Primary outcomes

1

Description
anxiety

Timepoint
at the time of entering the study-- when admitted to the labor sector

Method of measurement
Spielberger anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Saffron capsule In this research, Goldaro Company produced 50 g of weighed saffron powder with powdered electric pulp and percolated with 70% alcohol percolation for 72 hours extraction. Then, it was mixed with 105 grams of excipient and 0.52 grams of magnesium stearate to smooth the granule in an electric mixer. The resulting granules were then injected into a laboratory filling machine and 250 mg capsules of the above granules were prepared.

Category
Treatment - Drugs

2

Description
Placebo Capsule In order to remove the bias in the control group, the placebo containing 250 mg of lactose powder was prepared

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

the hospital and Darul-Shafa Hospital of Zahraye Marzieh in Isfahan city

Full name of responsible person

Street address

Hospital and Dar ul-Shafa Hazrat Zahraye Marzieh (SA)- Sahib Ibn Abbad Alley- Ghods Square- 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

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Giti Ozgoli

Position

Assistant Professor

Other areas of specialty/work

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Position

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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