Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of saffron oral capsules on pain severity and duration of the active phase of labor first stage

Protocol summary

Summary

Triple blind study to determine the effect of oral capsules of saffron on the severity and duration of the active phase of labor. The main inclusion criteria: nulliparous , 18-35 years, body mass index 5/19 to 30, gestational age 37-42 weeks, dilatation 3-4 cm cervical, cephalic presentation. Main exclusion criteria: using any herbal drug during the past 48 hours, addiction or using a variety of tobacco and alcohol, the risk of pregnancy complications, or history of any systemic illness or mental disease, the fetus with maternal pelvic disproportion, abnormal fetal heart rate, obstetric complications , cesarean indication, allergic reaction to the saffron Study Population, all nulliparous women that go to the hospital for delivery. Sample size:60. In the beginning of the study, one capsule (Saffron or placebo which is determined with a code), is given to the subjects for oral consumption. Pain severity was measured each hour until the end of active phase of first stage. Uterine contraction pattern is recorded every 30 minutes using tocodinamometer. Considering to the pattern of uterine contractions, fetal heart rate and the mother's vital signs, drug dose was repeated every 2 hours up to a maximum of three doses. If the dilation was according to the pattern of uterine contractions, the next dose of capsule is not used. If uterine contractions were hypertone , poor progress in labor or need to pain relief by pharmacological methods, appropriate measurement is performed and she is excluded from study

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205229830N1**
Registration date: **2014-03-10, 1392/12/19**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-03-10, 1392/12/19

Registrant information

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Sedigheh Ahmadi
Name of organization / entity
Mashhsd University Of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Mashhad University of Medical Sciences

Expected recruitment start date

2013-11-06, 1392/08/15

Expected recruitment end date

2014-03-06, 1392/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of saffron oral capsules on pain severity and duration of the active phase of labor first stage

Public title

Evaluation of the effect of saffron oral capsules on pain severity and labor duration

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Completing the written informed consent to participate in the study؛age of 18-35 years; body mass index of 19.5- 30;gestational age of 37-42 weeks; having no history of pregnancy more than 20 weeks of gestation; singleton pregnancy; cervical dilatation of 3-4 cm; cephalic presentation. Exclusion criteria: using any herbal drug during the past 48 hours; addiction or using a variety of tobacco and alcohol; maternal pregnancy complications (preeclampsia, bleeding during pregnancy, threat to abortion, premature rupture of fetus membranes more than 12 hours before admission of mother), having or history of any systemic disease (diabetes, hypertension, heart and kidney disease, etc), history of mental disorder, speaking, hearing and mental disorder, disproportion of maternal pelvic with fetal head; estimated fetal weight less than 2500 g and more than 4000 g (according to Johnson rules); fetal heart rate abnormalities; any abnormalities in the fetus (based on sonography; obstetric problems; multiple pregnancy; previous surgery on the uterus; cervix and delivery canal; cesarean indication; allergic reaction to the saffron
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)
Not 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
Mashhad University Of Medical Sciences
Street address
Mashhad University Of Medical Sciences
City
Mashhad
Postal code
8564917794
Approval date
2013-06-22, 1392/04/01
Ethics committee reference number
911184

Health conditions studied

1

Description of health condition studied
delivery
ICD-10 code
O80.8
ICD-10 code description
Other single spontaneous delivery

Primary outcomes

1

Description
pain intensity of labor
Timepoint
1 hour intervals during the intervention.
Method of measurement
Pain intensity using a visual pain scale

2

Description
Duration of the active phase of labor first stage
Timepoint
1-2 hour intervals during the intervention
Method of measurement
During the active phase of labor and vaginal exam registration

Secondary outcomes

1

Description
Uterine contractions
Timepoint
During each 30-minute intervention
Method of measurement
Tocodynamomtr device and touch the hand

Intervention groups

1

Description
Capsules 250 mg of the drug (saffron) every 2 hours and up to 3 doses, the intensity of uterine contractions and the progress of labor is consumed orally by the research unit
Category
Placebo

2

Description
Capsules 250 mg of the pelacebo every 2 hours and up to 3 doses, the intensity of uterine contractions and the progress of labor is consumed orally by the research unit
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Seventeen Ĭospitals September Mashhad - Social Security Organization
Full name of responsible person
Azhari - MSc in Nursing - Faculty of Nursing and Midwifery, Mashhad
Street address
Mashhsd University Of Medical Sciences
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Council of Mashhad University of Medical Sciences
Full name of responsible person
sedigheh Azhari
Street address
Mashhsd University Of Medical Sciences
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Council of Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Sedigheh Ahmadi
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Person responsible for updating data

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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