Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The effect of saffron syrup on the labor pain intensity, anxiety and duration of labor in primiparous women: a randomized controlled trial

Protocol summary

Summary

The aims of this double blind trial are to examine the effect of saffron syrup on labor pain severity and intensity of anxiety (primary outcomes) and duration of labor phases, hemoglobin, hematocrit, delivery experience score, woman satisfaction, amount of oxytocin used, and newborn bilirubin (secondary outcomes) in primiparous women. Ninety six low- risk women with gestational age of 38 to 41 weeks, referring to the 29 Bahman hospital in Tabriz, will be randomized into one of three groups: each receiving 80 to 240 ml syrup; containing 250 to 750 mg saffron and palm sugar, 250 to 750 mg saffron and artificial sugar, or placebo; using block randomization with block sizes of 3, 6 and 9, determined with a computerized program. A person not involved in the recruitment and data collection will determine allocation sequence and will number bottles containing the syrups identical in terms of color, taste and smell. After getting written informed consent and gathering baseline data, participants will take 80 ml of the syrup (made by Yashil drug company, Aras) when cervical dilation is around 3 to 4 cm and there are at least three uterine contractions in 10 minutes lasting for 45 to 60 seconds. It will be repeated every two hours for maximum three doses considering pain intensity, uterine contraction, and pattern of fetal heart rate. Severity of pain will be assessed using pain visual analogue scale (VAS) and intensity of anxiety will be examined by the state Spielberger inventory and VAS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507073706N26**
Registration date: **2016-02-03, 1394/11/14**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-02-03, 1394/11/14

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

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

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-02-01, 1394/11/12

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of saffron syrup on the labor pain intensity, anxiety and duration of labor in primiparous women: a randomized controlled trial

Public title

The effect of saffron syrup on the labor pain intensity, anxiety and duration of labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged 18 to 35 years; nulliparous; gestational age of 38 to 41 weeks; spontaneous onset of labor; singleton pregnancy with estimated fetal weight of 2500 to 4000 grams and cephalic presentation; no use of any herbal and anti anxiety drugs in the past 12 hours; reactive non stress test; body mass index of 19.8 to 30 kg/m²; having 8 years education or higher. Exclusion criteria: history of surgery on the uterus, cervix or vagina; allergy to saffron; known chronic diseases including hypertension, diabetes, diseases of the respiratory, cardiovascular, endocrine, etc.; history of mental illnesses; speech, hearing, visual or mental problems; known indications for caesarean section; premature rupture of membranes for more than 12 hours; any known fetal abnormalities; known fetal growth retardation

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Research Deputy, 3rd floor, Centeral building No 2 , Tabriz University of Medical Sciences, Golgasht St., Tabriz

City

Tabriz

Postal code

Approval date

2015-12-07, 1394/09/16

Ethics committee reference number

TBZMED.REC.1394.780

Health conditions studied

1

Description of health condition studied

Normal labor and delivery

ICD-10 code

080.0

ICD-10 code description

Spontaneous vertex delivery

Primary outcomes

1

Description

Severity of labor pain

Timepoint

every one hour from about 3 cm cervical dilation to the end of the second stage of labor; one and 18 to 24 hours after delivery

Method of measurement

visual analogue scale (VAS) for pain

2

Description

Intensity of anxiety

Timepoint

at baseline, 3 to 4 hours after starting intervention, and 18 to 24 postpartum

Method of measurement

Spielberger state questionnaire and visual analogue scale for anexity

Secondary outcomes

1

Description

Duration of first stage of labor (active phase)

Timepoint

from 4 cm to 10 cm cervical dilatation

Method of measurement

Partogramm form

2

Description

Duration of second stage of labor

Timepoint

from 10 cm cervical dilation to delivery

Method of measurement

Partogramm form

3

Description

Duration of third stage of labor

Timepoint

immediately after birth to expultion of placenta and fetal membranes

Method of measurement
Partogramm form

4

Description
Hemoglobin
Timepoint
at baseline and 18 to 24 hours after birth
Method of measurement
labratory test

5

Description
Score of delivery experience
Timepoint
18 to 24 hour after delivery
Method of measurement
delivery experience questionnaire

6

Description
Woman satisfaction rate
Timepoint
18 to 24 hour after delivery
Method of measurement
one question with likert options

7

Description
Amount of oxytocin used
Timepoint
during the intervention
Method of measurement
observation

8

Description
Hematocrit
Timepoint
at baseline and 18 to 24 hours after birth
Method of measurement
labratory test

9

Description
Newborn bilirubin
Timepoint
18 to 24 hours after delivery
Method of measurement
Billi Check device

Intervention groups

1

Description
The first intervention group: 80 to 240 ml syrup (made by Yashil drug company, Aras)containing 750 mg saffron and 200 mg of sugar palms in 240 ml syrup. 80 ml of the syrup will be taken when cervical dilation is around 3 to 4 cm and there are at least 3 uterine contractions in 10 minutes lasting for 45 to 60 seconds. It will be repeated every two hours for maximum three doses considering pain intensity, uterine contraction, and pattern of fetal heart rate.
Category
Treatment - Drugs

2

Description
The second intervention group: 80 to 240 ml syrup (made by Yashil drug company, Aras) containing 750 mg saffron and artificial sugar (Isonalt) in 240 ml syrup. 80 ml of the syrup will be taken when cervical dilation is around 3 to 4 cm and there are at least 3 uterine contractions in 10 minutes lasting for 45 to 60 seconds. It will be repeated every two hours for maximum three doses considering pain intensity, uterine contraction, and pattern of fetal heart rate.
Category
Treatment - Drugs

3

Description
Control group: 80 to 240 ml syrup (made by Yashil drug company, Aras) containing placebo of saffron and artificial sugar (Isonalt) in 240 ml syrup (identical in color, smell and taste with the saffron syrups. 80 ml of the syrup will be taken when cervical dilation is around 3 to 4 cm and there are at least 3 uterine contractions in 10 minutes lasting for 45 to 60 seconds. It will be repeated every two hours for maximum three doses considering pain intensity, uterine contraction, and pattern of fetal heart.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
29 Bahman Hospital, Tabriz
Full name of responsible person
Roghayeh Mohammadie Rad
Street address
29 Bahman Hospital, 29 Bahman Blvd, Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person
Mohammad-Reza Rashidi

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Research Deputy, 3rd floor, Centeral building No 2 , Tabriz University of Medical Sciences, Golgasht st; Tabriz

City
Tabriz

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, 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
Nursing & Midwifery Faculty, Tabriz University of Medical Sciences

Full name of responsible person
Roghayeh mohammadie rad

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Person responsible for scientific inquiries

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Sakineh Mohammad-Alizadeh-Charandabi

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PhD in Reproductive Health

Other areas of specialty/work

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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