

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Comparison the effect of oral consumption of Date syrup with Honey Saffron syrup on progress of delivery in primiparous women

#### Protocol summary

##### Study aim

Comparison the effect of oral consumption of Date syrup with Honey Saffron syrup on progress of delivery in primiparous women admitted to the delivery ward of Besat Hospital in sanandaj, 2019

##### Design

This study is a randomized clinical trial. Number of sample will be 180 and includes one control group and two intervention groups.

##### Settings and conduct

The study will be performed in the delivery department. Professor of emirates is not aware of the type of intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to cooperate, cervical dilatation 4 cm when entering the study, age between 18 to 35, single pregnancy, gestational age between 37 to 42 weeks, no indication of cesarean section, absence of fetal distress, no rupture of the membrane when entering the study, having physiological labor and delivery conditions. Exclusion criteria: unwillingness to continue collaborating in the study process, entering labor and nonphysiological conditions, precipitous labor, use of epidural anesthesia, fetus distress, meconium disposal, nausea and vomiting

##### Intervention groups

Group of date syrup: 6 milled dates with 150 ml of water which after clearing the filter are completely transparent and prepared in 150 cc jars. Group of honey saffron syrup: 250 mg of saffron and 2/5 teaspoons of honey plus 150 ml of water are dissolved in 150 cc jars. Control group: The usual care is given to the client and only plain water is provided if desired.

##### Main outcome variables

Duration of first, second and third of labor

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190924044873N1**  
Registration date: **2020-01-12, 1398/10/22**  
Registration timing: **registered\_while\_recruiting**

Last update: **2020-01-12, 1398/10/22**

Update count: **0**

##### Registration date

2020-01-12, 1398/10/22

##### Registrant information

##### Name

Hana Sohrabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3366 4645

##### Email address

hana.sohrabi@muk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-01, 1398/08/10

##### Expected recruitment end date

2020-02-29, 1398/12/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of oral consumption of Date syrup with Honey Saffron syrup on progress of delivery in primiparous women

**Public title**

Comparison the effect of oral consumption of Date syrup with Honey Saffron syrup on progress of delivery

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Willingness to cooperate Cervical dilatation 4 cm when entering the study Age between 18-35 Single pregnancy with cephalic presentation Gestational age between 37-42 weeks Estimated fetal weight between 2500-4000 gr No indication of cesarean section Absence of fetal distress No rupture of the membrane when entering the study Lack of known systemic diseases No pregnancy complication such as preeclampsia, bleeding and infection Having no history of infertility Having physiological labor and delivery conditions Have physical and mental health No sensitivity to Dates, Honey and Saffron

**Exclusion criteria:**

Unwillingness to continue collaborating in the study process Entering labor and nonphysiological conditions Precipitous labor Use of epidural anesthesia Fetus distress Meconium disposal Nausea and vomiting

**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: **180**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Persons will be divided in to Honey Saffron syrup group, Palm syrup group and Control group according to simple randomization and envelopes. Participants will be given three envelopes in the package and selected by each of them to be placed in the respective group. It should be noted that it will be written in three envelopes of the group type ( Saffron syrup, Date palm syrup and Control group).

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Kurdistan University of Medical Sciences.

**Street address**

Sanandaj.Pasdaran Street. Kurdistan University of Medical Sciences. School of Nursing and Midwifery.

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617913446

**Approval date**

2019-10-01, 1398/07/09

**Ethics committee reference number**

IR.MUK.REC.1398.149

**Health conditions studied****1****Description of health condition studied**

Progress of delivery

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Progress of childbirth

**Timepoint**

Vaginal examinations will be done at baseline and then in the active phase of the first phase of the labor every 2 hours and in the second phase of the labor every 30 minutes. The recording of uterine contractions and fetal heart rate at baseline will be active every 30 minutes in the first phase of labor and every 15 minutes in the second phase.

**Method of measurement**

Partograph form

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Honey saffron syrup group: Honey saffron syrup is made by Kurdistan Shafa medicine company. 250 ml of saffron and 2/5 teaspoons of honey from one of the prestigious factories ( for all sample of the same type) in 150 ml of maxed water are used. The syrup are made in opaque glass.The presentation of syrups at beginning of the study (4 cm dilatation) and

then every 30 to 60 minutes is extended once the active phase of the first phase of labor is delivered as the patient wishes.

**Category**

Prevention

**2****Description**

Intervention group: Date syrup group: Date syrup is made by Kurdistan Shafa medicine company. Thus, to prepare it, 6 Bam black dates (same weight for all samples) after extracting the core in the blender thoroughly mix and then pass through the filter and completely smooth and without scrubbing mixed in 150.

**Category**

Prevention

**3****Description**

Control group: Routine care is done.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Besat Hospital

**Full name of responsible person**

Roonak Shahoei

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Sanandaj, Pasdaran Street, Kurdistan University of Medical Sciences.

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Ebrahim Ghaderi

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Sanandaj University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Roonak Shahoei

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Roonak Shahoei

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

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Sanandaj University of Medical Sciences

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Roonak Shahoei

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

All data is shared after anonymization.

**When the data will become available and for how long**

The access period beings 6 months after the results are published.

**To whom data/document is available**

Data will be available only to researchers working in academic and research institutions.

**Under which criteria data/document could be used**

Access to data requires compliance with professional ethics.

**From where data/document is obtainable**

Applicants can refer to the library of the School of Nutsing and Midwifery Kurdistan University of Medical Sciences or Dr. Roonak Shaoei for information.

Address:Kurdistan University of Medical Sciences.

Email:Rshaho@yahoo.com tel:087-33627636

**What processes are involved for a request to access data/document**

The applicant can access the documents after the article is published.

**Comments**