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 be180 and includes one control group and two intervention groups.

Settings and conduct
The study will be performd in the delivery department. professot of emirares 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 between18 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 saffran 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)

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+98 87 3366 4645

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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 begining of the study (4 cm dilatation) and

then every 30 to 60 minutes is extended once thr acrive 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, Kurdestan 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

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Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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Contact

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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