Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of honey saffron syrup on the progress of labor in nulliparous women admitted to childbirth ward of Imam Khomeini Hospital of Divandarreh in 2018

Protocol summary

Study aim

Determination of the effect of honey saffron syrup on the development of labor in primiparous women of Imam Khomeini Hospital of Divandareh in 2018

Design

Clinical trials; 90 specimens; Randomization; intervention groups 1 and 2; control group; using closed packages; Double blind

Settings and conduct

Researcher and research units are blind; Maternity ward of Imam Khomeini hospital

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 18-35 years; nulliparous; Gestational age 38-41 weeks; Spontaneous labor; Estimated fetal weight 2500 - 4000 grams; Cephalic presentation; Singleton; BMI 19.8 - 30 kg / m2; Reactive non-stress test; no use of oral glucose lowering drugs and insulin; anti-coagulants; nonsteroidal anti-inflammatory drugs; hypotensive drugs; benzodiazepines; barbiturates; narcotics; antidepressants and alcohol. like to participate in the study. Exclusion Criteria: History of uterus, cervix and vagina surgery; indications for cesarean section (abrupt; lack of progress; meconium aspiration; narrow pelvis; fetal distress); any abnormality in fetus; growth restriction and cardiovascular disease in fetus; Saffron sensitivity; History of mental illness; speech; hearing; visual and mental problems, mother's involvement in chronic and systemic diseases including increased blood pressure; diabetes; respiratory; cardiovascular; liver and endocrine diseases; crossing more than 12 hours of rupture of membranes; Unwilling to continue participation in the study

Intervention groups

First intervention group: Syrup prepared as a solution of 750 mg of saffron and 75 g of honey plus 450 ml of water Second intervention group: Syrup prepared as a combination of 750 mg of saffron and artificial sugar (15 g saccharin) with 450 ml of water Control group: Placebo syrup

Main outcome variables

Reduce the duration of the first, second and third stage of labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171210037807N1**
Registration date: **2018-04-27, 1397/02/07**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-27, 1397/02/07**
Update count: **0**

Registration date

2018-04-27, 1397/02/07

Registrant information

Name

sheno ghaderi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3362 7228

Email address

ghaderi.sheno@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2018-09-05, 1397/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of honey saffron syrup on the progress of labor in nulliparous women admitted to childbirth ward of Imam Khomeini Hospital of Divandarreh in 2018

Public title

Effect of honey saffron syrup on the progress of labor in nulliparous women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 35-18 years nulliparous Gestational age 38-41 weeks Spontaneous labor Estimated estimated fetal weight by the examiner or ultrasound of 2500 - 4000 grams Cephalic presentation Singleton The body mass index is 19.8 - 30 kg / m2 Reactive non-stress test The mother did not use oral and insulin glucose lowering drugs, anti-coagulants, nonsteroidal anti-inflammatory drugs, hypotensive drugs and drugs, benzodiazepines, barbiturates, narcotics, antidepressants, and alcohol. Willing to participate in the study

Exclusion criteria:

History of surgery on the uterus, cervix and delivery duct There are indications for cesarean section (abrupt, lack of progress, meconium, narrow pelvis, fetal distress) Fetus to any abnormalities, growth restriction and cardiovascular disease (fetus) Saffron sensitivity History of or mental illness, speech, hearing, visual and mental problems, mother's involvement in chronic and systemic diseases including increased blood pressure, diabetes, respiratory, cardiovascular, liver and endocrine diseases rupture of membranes more than 12 hours mother not willing to contine the study

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using envelopes in the package will be allocated to three groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Syrups will be shed in dishes of similar shape and color and the color of the syrups is the same in the three groups and encoded by the pharmacist. The codes will be provided to the supervisor only so the researcher and the research units will be unaware of the codes.

Placebo

Used

Assignment

Other

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

Pasdaran street

City

Sanandaj

Province

Kurdistan

Postal code

666147 - 13446

Approval date

2018-03-14, 1396/12/23

Ethics committee reference number

IR.MUK.REC.1396.368

Health conditions studied

1

Description of health condition studied

Childbirth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

First stage of labor

Timepoint

The length of the first stage of labor, from 4 cm to 10 cm dilatation

Method of measurement

Timer

2

Description

Second stage of labor
Timepoint
The length of the second stage of labor from 10 cm dilatation to the exit of the embryo head
Method of measurement
timer

3

Description
Third stage of labor
Timepoint
Third stage of labor from exit of newborn to exit of placenta
Method of measurement
timer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Syrup prepared as a solution of 750 mg of saffron and 75 g of honey plus 450 ml of water
Category
Treatment - Drugs

2

Description
Intervention group: Syrup prepared as a combination of 750 mg of saffron and artificial sugar (15 g sodium saccharin) with 450 ml of water
Category
Treatment - Drugs

3

Description
Control group: Syrup with the same color as intervention wedges and no calories
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Sheno Ghaderi
Street address
Imam Khomeini Street
City
Divandareh
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Kurdistan
Postal code
6648456485
Phone
+98 87 3872 2930
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ghaderi.sheno1366sg@gmail.com
Web page address
http://www.muk.ac.ir/Muk/Hospitals/Imam_Divandare.aspx

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Roonak Shahooie
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Pasdaran Street
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Email
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Web page address
http://www.muk.ac.ir/Muk.aspx
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 shahoie
Position
Professor

Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
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Person responsible for updating data

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Web page address
http://www.muk.ac.ir/Muk.aspx

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available