Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of oral evening primrose capsules on ripening of the cervix and progress of delivery in primiparous women

Protocol summary

Study aim

Effect of oral evening primrose capsules on ripening of the cervix and progress of delivery in primiparous women referring to selected centers in sanandj, 2020

Design

This research will be conducted with the one-blind randomized trial method on 112 primiparous women referring to selected centers in sanandj. Samples will be divided into two equal groups of medicine and placebo with the randomized allocation method.

Settings and conduct

The study will be conducted in the office of two obstetricians and the Besat Hospital, and participants is not aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Conditions for entering the study: - Willingness to participate in the study -Being primiparous -Literacy for reading and writing -Age 18 to 35 years old -Term pregnancy age based on first trimester ultrasound -Single pregnancy whit cephalic presentation -live fetus -Having a normal pelvis with a gynecologist's diagnosis -The estimated weight of the fetus is between 4000-2500 gr -Bishop score lower than or equal to 4 -Intact membranes -Healthy pregnant women -No ban on the use of evening primrose oil -No structural cervical anomalies -Height above 150 cm -Lack of alcohol and opioids -Avoid using laxatives and any herbal medication prior to study Conditions for not entering the study: -Mother's unwillingness to continue cooperation in the research -Consumption of less than two capsules per day -Use of epidural anesthesia -Cesarean delivery

Intervention groups

Intervention group: Each of the participants in the intervention group given to a bottle containing 14 1000mg oral evening primrose capsules. Control group: Each of the participants in the control group given to a bottle containing 14 plasbo capsules containing canola oil.

Main outcome variables

Ripening of the cervix, duration of the first stage, second and third stages of the labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200316046795N1**
Registration date: **2020-04-19, 1399/01/31**
Registration timing: **prospective**

Last update: **2020-04-19, 1399/01/31**
Update count: **0**

Registration date

2020-04-19, 1399/01/31

Registrant information

Name

Fatemeh Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 4233 4511

Email address

fateme.mohamadi@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-10-06, 1399/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of oral evening primrose capsules on ripening of the cervix and progress of delivery in primiparous women

Public title
Effect of oral evening primrose capsules on ripening of the cervix and progress of delivery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the study Being primiparous Literacy for reading and writing Age 18 to 35 years old Term pregnancy age (gestational age 39 weeks to 39 weeks and 6 days) based on first trimester ultrasound Single-pregnancy whit cephalic presentation live fetus Having a normal pelvis with a gynecologist's diagnosis The estimated weight of the fetus is between 4000-2500 grams Bishop score lower than or equal to 4 Intact membranes Healthy pregnant women (without known disease, surgery or pregnancy complications such as placental abruption, placenta previa or vasoprevia , preeclampsia or no fetal anomaly) No ban on the use of evening primrose oil (hemorrhagic disorders, consuming anticoagulants, individuals with a history of schizophrenia, epilepsy and consumer phenothiazine) No structural cervical anomalies Height above 150 cm Lack of alcohol and opioids Avoid using laxatives and any herbal medication prior to study

Exclusion criteria:
Mother's unwillingness to continue cooperation in the research Consumption of less than two capsules per day (problems with checklist of oral capsules) Use of epidural anesthesia Cesarean delivery

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

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **112**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals will be divided into intervention and control groups using the quadratic block formation method. A code to intervention (using capsules of evening primrose) and Code B to the control group (using placebo) will be allocated. The four blocks will then be sampled in six different modes (AABB, ABAB, ABBA, BBAA, BABA and BAAB).

Blinding (investigator's opinion)
Single blinded

Blinding description
This research is a with the one-blind randomized trial method (participants will be unaware of the contents of the capsules). For this purpose to observe the ethical issues of the research, after the necessary explanations about the purpose and how to conduct the study to pregnant mothers, informed consent is obtained from them. Samples are divided into two equal groups of medicine and placebo with the randomized allocation method. Each of the participants will be given a bottle containing 14 1000mg oral evening primrose capsules (2 capsules per day, each 12 twelve hours for a week) or the placebo containing 14 placebo capsules containing canola oil. The color and shape of these capsules are similar to the intervention group.

Placebo
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
2020-03-15, 1398/12/25

Ethics committee reference number
IR.MUK.REC.1398.309

Health conditions studied

1

Description of health condition studied
Ripening of the cervix and progress of labor

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Ripening of the cervix

Timepoint

Bishop score is recorded at the beginning of the study and then, if there are no labor symptoms, the Bishop score is measured again after one week.

Method of measurement

The second part of the questionnaire:Midwifery Specifications (Bishap Score)

2

Description

Labor progress

Timepoint

Registration of vaginal examinations at the beginning of the study and then in the active phase of the first stage of labor will be done every 2 hours and in the second stage of labor every 30 minutes. The registration of uterine contractions and fetal heart rate at the beginning of the study will be once every 30 minutes in the active phase of the first stage of labor and once every 15 minutes in the second stage of labor.

Method of measurement

The third part of the questionnaire (delivery details)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Capsule of evening primrose oil group: Evening primrose oil capsules are produced by pharmaceutical companies Barij. Providing a capsule in the beginning of the study, if the criteria for entry into the study. Each of the participants in the intervention group given to a bottle containing 14 1000mg oral evening primrose capsules (2 capsules per day, each 12 twelve hours for a week).

Category

Prevention

2

Description

Control group: Placebo group: The capsules used for the control group are prepared by the researcher that the color and shape of these capsules are similar to the intervention group. Providing a capsule in the beginning of the study, if the criteria for entry into the study. Each of the participants in the control group given to a bottle containing 14 plasbo capsules containing canola oil (2 capsules per day, each 12 twelve hours for a week).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Sholeh Shah Ghaibi's office

Full name of responsible person

Roonak Shahoei

Street address

Sanandaj, Pasdaran Street, Kurdistan University of Medical Sciences

City

Sanandaj

Province

Kurdistan

Postal code

6617913448

Phone

+98 87 3362 7636

Fax

+98 87 3366 0092

Email

Rshaho@yahoo.com

2

Recruitment center

Name of recruitment center

Dr. Fariba Farhadifar's office

Full name of responsible person

Roonak Shahoei

Street address

Sanandaj, Pasdaran Street, Kurdistan University of Medical Sciences

City

Sanandaj

Province

Kurdistan

Postal code

6617913448

Phone

+98 87 3362 7636

Fax

+98 87 3366 0092

Email

Rshaho@yahoo.com

3

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Roonak Shahoei

Street address

Sanandaj, Pasdaran Street, Kurdistan University of Medical Sciences

City

Sanandaj

Province

Kurdistan

Postal code

6617913448

Phone

+98 87 3362 7636

Fax

+98 87 3366 0092

Email
Rshaho@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Ebrahim Ghaderi
Street address
Sanandaj, Pasdaran Street, Kurdistan University of Medical Sciences
City
Sanandaj
Province
Kurdistan
Postal code
6617913448
Phone
+98 87 3362 7636
Fax
+98 87 3366 0092
Email
Rshaho@yahoo.com
Web page address
http://www.muk.ac.ir/Page?pageId=33
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
Street address
Sanandaj, Pasdaran Street, Kurdistan University of Medical Sciences, School of Nursing and Midwifery
City
Sanandaj
Province
Kurdistan
Postal code
6617913448
Phone
+98 87 3362 7636
Fax
+98 87 3366 0092
Email
Rshaho@yahoo.com

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
Midwifery
Street address
Sanandaj, Pasdaran Street, Kurdistan University of Medical Sciences, School of Nursing and Midwifery
City
Sanandaj
Province
Kurdistan
Postal code
6617913448
Phone
+98 87 3362 7636
Fax
+98 87 3366 0092
Email
Rshaho@yahoo.com

Person responsible for updating data

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
Street address
Sanandaj, Pasdaran Street, Kurdistan University of Medical Sciences, School of Nursing and Midwifery
City

Sanandaj
Province
Kurdistan
Postal code
6617913446
Phone
+98 87 3362 7636
Fax
+98 87 3366 0092
Email
Rshaho@yahoo.com

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 can be shared after persons have not been recognized.
When the data will become available and for how long
Data access is 6 months after publish the results.
To whom data/document is available
Data will only be available to researchers working at academic and scientific institutions.
Under which criteria data/document could be used
Access to data requires observe of professional ethics fundamental.
From where data/document is obtainable
Applicants can refer to the library of the Faculty of Nursing and Midwifery of Kurdistan University of Medical Sciences or Dr. Roonak Shahoei to receive the data. Address: Kurdistan University of Medical Sciences Email: Rshao@yahoo.com Phone:087- 33627636
What processes are involved for a request to access data/document
The documents applicant can access that after the article is published.
Comments