Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparision between the effects of castor oil and evening primrose oil on cervical ripening of Nuli Par women

Protocol summary

Study aim
Comparative determination of the effect of evening primrose and castor oil on cervical readiness in Noli Par women

Design
The research is a parallel quasi-experimental clinical trial. In this study, the information is in three groups, in group A (60 cc of castor oil), group B (1000 mg vaginal capsule of evening primrose) and in group C (control). No intervention is performed. Therefore, the present study is a study of three, with a test plan before and after.

Settings and conduct
The researcher, all mothers of 38 weeks of Noli Par, under the supervision of the doctor in question, are referred to the midwifery triage unit of Afshar Hospital for evaluation of inclusion and exclusion criteria. And evaluates the exit and determines the bishop score and asks the mothers to come again on the day of EDC (40th week of pregnancy). the samples are selected and then by the table of random numbers the samples are placed in three groups A, B and C In group A, 60 cc of castor oil is produced, in group B, 1000 mg vaginal evening primrose capsule is produced, and in group C, which is controlled.There is no intervention other than routine treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria : Iranian citizen Single twin BiShop scorebelow four Tendency to have a normal delivery Having a low-risk pregnancy Exclusion criteria: Use of any drugs or herbal medicines Any vaginal bleeding Having contractions Having a private midwife

Intervention groups
The samples are in groups A, B and C. In group A: 60 cc of castor oil, in group B: evening primrose (1000 mg vaginal evening primrose capsule) and in group C, which is controlled, no intervention other than routine care. It does not happen

Main outcome variables
Cervical ripening

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160809029281N3**
Registration date: **2022-12-16, 1401/09/25**
Registration timing: **retrospective**

Last update: **2022-12-16, 1401/09/25**
Update count: **0**

Registration date
2022-12-16, 1401/09/25

Registrant information

Name
Fateme Moshirenia

Name of organization / entity
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-13, 1400/09/22

Expected recruitment end date
2022-01-12, 1400/10/22

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparision between the effects of castor oil and evening primrose oil on cervical ripening of Nuli Par women

Public title
Evaluation of the effect of castor oil and evening primrose on cervical ripening

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Iranian citizenship Single twin BiShop score below four4 Tend to have a normal delivery a low-risk pregnancy (no diabetes, no preeclampsia, bleeding, etc.) Age 18-35 years Having h eight shorter than 150 cm Water bag closed Fetal weight according to sono2500-4000 No bleeding diseases Head displayFetal health according to sono Fetal health according to sono No known or systemic chronic diseases in the mother

Exclusion criteria:
Use of any narcotics or herbal medicines Any vaginal bleeding Having a midwife with a private

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

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **114**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples will be selected by easy sampling method and then they will be randomly divided into three groups: intervention 1 (60 cc of castor oil), intervention 2 (1000 cc of evening primrose vaginal capsule) and group 3 (control). And then the random allocation of samples will be such that 114 envelopes will be prepared and named equally with code 1, 2, and 3. The codes will be inside the envelopes and will be closed in the envelopes. Those who choose envelopes with code 1 will be in intervention group 1, those who choose envelopes with code 2 will be in intervention group 2, and those who will choose envelopes with code 3 will be in the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants do not know how to intervene.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Research Infertility Research Center - Shahid Sadoughi University of Medical Sci

Street address
Timsar fallahi Ave.,yazd Town

City
yazd

Province
Yazd

Postal code
8943163589

Approval date
2021-10-31, 1400/08/09

Ethics committee reference number
IR.SSU.RSI.REC.1400.015

Health conditions studied

1

Description of health condition studied
cervix ripening

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Cervical ripening

Timepoint
40 weeks of pregnancy, 48 hours after intervention

Method of measurement
Determine the B-score score, which includes five characteristics: dilatation, effusion, fetal position, consistency, and cervical condition. The most common scoring system is to predict the success or failure of induction of labor.

Secondary outcomes

empty

Intervention groups

1

Description
After taking a stress-free test, the researcher is given group A 60 cc of castor oil (produced by Dineh Aromatic Company). Avoid other traditional methods to start labor and danger signs are taught according to the national protocol. The researcher provides the follow-up form to the samples. The subjects in each group are rejected up to 48 hours after the intervention in such a way that every 6-8 hours during the telephone call, the onset of

contractions is asked in case of contractions (length one). At least 8 hours of contractions) refer to the desired hospitals and if the contractions do not start within 48 hours after the intervention, the research units in all three groups refer to selected hospitals for hospitalization.

Category

Treatment - Other

2

Description

Group B is given 1000 mg vaginal evening primrose capsule (Amin Iran Pharmaceutical Company). The dose of drugs is determined according to the studies performed by the pharmaceutical specialists of Amin Pharmaceutical Company and Dineh Iran Industrial Complex. Traditional abstinence to begin childbirth and danger signs are taught according to national protocol. The researcher provides the follow-up form to the samples. The subjects in each group are rejected up to 48 hours after the intervention in such a way that every 6-8 hours during the telephone call, the onset of contractions is asked in case of contractions (length one). At least 8 hours of contractions) refer to the desired hospitals and if the contractions do not start within 48 hours after the intervention, the research units in all three groups refer to selected hospitals for hospitalization.

Category

Treatment - Other

3

Description

Control group: group C does not involve any intervention other than routine treatment. Research units are instructed to avoid enema, laxatives, herbal or chemical drugs, or other traditional methods of initiating labor during this period, and danger signs are taught according to the national protocol. The researcher provides the follow-up form to the samples. The subjects in each group are rejected up to 48 hours after the intervention in such a way that every 6-8 hours during the telephone call, the onset of contractions is asked in case of contractions (length one). At least 8 hours of contractions) refer to the desired hospitals and if the contractions do not start within 48 hours after the intervention, the research units in all three groups refer to selected hospitals for hospitalization

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Afshar Hospital

Full name of responsible person

Fateme Moshirenia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Fateme Moshirenia

Position

Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available