Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Elaeagnus angustifolia fruit extract capsule on childbirth after-pains among multiparous women

Protocol summary

Study aim
Determination of the effect of Elaeagnus angustifolia fruit extract capsule on childbirth after-pains among multiparous women

Design
A randomized clinical trial with control group, in a parallel, three-way, blind, randomized on 105 women in the postpartum period, who were selected as available, and randomization is done using the website www.randomization.com. Each of the groups of Elaeagnus angustifolia fruit extract, placebo and Mefenamic acid are included.

Settings and conduct
People inter the study 2 hours after delivery. In the Elaeagnus angustifolia fruit extract, one capsule of 500 mg of Elaeagnus angustifolia fruit extract and in the placebo group, a placebo is given to the individual every 6 hours to 24 hours, and one hour after each drug dose, their pain will be measured. In the mefenamic acid group, mefenamic acid will be given if necessary according to the routine of Ommolbanin hospital, and the number of mefenamic acid used and their pain will be measured as in other groups. the research unit and the statistical analyst will not know about the codes related to the Elaeagnus angustifolia fruit extract capsule, placebo and mefenamic acid and which group each of the research units are placed in.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: the second to fourth birth. Normal delivery and full term, The baby's weight between 2500-4000 grams, Not to be allergic to Elaeagnus angustifolia, Exclusion Criteria: The impossibility of continuing to breastfeed the baby, Any problem that disturbs the routine care of the mother.

Intervention groups
In the intervention groups, there are Elaeagnus angustifolia fruit extract capsule and placebo (containing Avicel powder) and in the control group there is Mefenamic acid based on routine hospital care.

Main outcome variables
childbirth after-pains

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230608058428N1**
Registration date: **2023-06-22, 1402/04/01**
Registration timing: **prospective**

Last update: **2023-06-22, 1402/04/01**
Update count: **0**

Registration date
2023-06-22, 1402/04/01

Registrant information

Name
Seyedeh Parvin Zabeti Asnad Astaneh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2024-02-20, 1402/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Elaeagnus angustifolia fruit extract capsule on childbirth after-pains among multiparous women

Public title
Evaluation of the effect of Elaeagnus angustifolia extract on after-pains

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
have the desire to enter the study. age between 18 to 35 years old. At least be literate in reading and writing. The current birth be the second to fourth birth. Normal delivery, singleton and full term. (Based on the ultrasound of the first trimester or last menstrual valid period) The baby be alive and healthy. If there are pains with a score of 4 to 10 based on the pain ruler. Cephalic presentation. The baby's weight should be 2500-4000 grams. (weighing recorded in the baby's file) Not to have any past medical and mental history. (heart disease, chronic Hypertension, and pre-eclampsia, diabetes, kidney and lung disease, autoimmune diseases and all types of neurological and mental diseases) Not to be allergic to Elaeagnus angustifolia. (Symptoms of allergy include: rhinitis, rhinoconjunctivitis, dermatitis) Not to be addicted to drugs, psychotropic substances, alcohol or tobacco. Not to have severe post partum bleeding after delivery.(Bleeding that requires medical measures (other than receiving centocinone) or requiring blood transfer and moving to operating room.) Not having any history of uterine surgery or caesarean section Drug analgesia has not been used to reduce labor pain.(Spinal, Epidural, Entonox gas) Not to have 3 and 4 perineum tears. The first, second, and third stages of labor should be normal.(First stage: no fast or slow progressing labor, no prolonged rupture of membranes (more than 12 hours), second stage: no instrumental labor, no third and fourth degree rupture, third stage: spontaneous exit of the placenta and membranes)

Exclusion criteria:
Not intend to continue the research Mother's refusal to take more than one capsule of Elaeagnus angustifolia or placebo The impossibility of continuing to breastfeed the baby (Due to the death of the baby, hospitalization in NICU) Any problem that disturbs the routine care of the mother.(Transferring the mother to the operating room-early discharge before 24 hours-hemorrhage or any obstetric problems of the mother that require treatment.)

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible women for the study are divided into 3 groups of Elaeagnus angustifolia fruit extract capsule, placebo and Mefenamic acid by random allocation and enter the study using the random sequence created by the random number table of the site www.randomization.com. In this way, the created random sequence is written on small sheets and kept in a closed envelope, and when each person chooses, the envelope door is opened and they enter each group based on the code (A, B, C).

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blind groups, the capsules of Elaeagnus angustifolia fruit extract and placebo and mefenamic acid are provided to the researcher by the pharmacist consultant in similar forms (appearance, color and packaging) with three different codes. Therefore, until the end of the study, the research unit and the statistical analyst will not know about the codes related to the Elaeagnus angustifolia fruit extract capsule, placebo and mefenamic acid and which group each of the research units are placed in.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences, School of Nursing and Midwifery

Street address
School of Nursing and Midwifery, Doctora Crossroads, Daneshgah Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Approval date
2023-06-06, 1402/03/16

Ethics committee reference number
IR.MUMS.NURSE.REC.1402.030

Health conditions studied

1

Description of health condition studied
after-pains after normal delivery
ICD-10 code
Z39.2
ICD-10 code description
Encounter for routine postpartum follow-up

Primary outcomes

1

Description
Severity of after pain
Timepoint
After 2 hours after delivery, Elaeagnus angustifolia fruit extract capsule or placebo is given to the mother every 6 hours to 24 hours, and the intensity of after pain is measured one hour after each drug dose.
Method of measurement
Painometer-visual analogue scale, which is one of the parts of the painometer tool, will be used to measure pain intensity.

2

Description
Quality of after pain
Timepoint
After 2 hours after delivery, Elaeagnus angustifolia fruit extract capsule or placebo are given to the mother every 6 hours, and the quality of after pain is measured one hour after receiving each drug dose.
Method of measurement
To evaluate the quality of pain, the word description scale index, which is one of the parts of the painometer tool, will be used.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Elaeagnus angustifolia will be purchased from centers approved by the Faculty of Iranian and Complementary Medicine, and after grinding, it will be soaked in 70% hydroalcoholic solvent for 2 days. Then, the obtained hydroalcoholic extract is filtered and after removing the solvent by placing it in a dryer, the final extract will be obtained. This dried extract is formulated as a capsule of 500 mg of whole elderberry fruit extract and will be given to mothers 2 hours after delivery, every 6 hours to 24 hours.
Category
Treatment - Drugs

2

Description
Intervention group: (The second intervention group) Using a placebo with similar capsules and cans, made in the pharmacology department of medicinal plants of Mashhad University of Medical Sciences, the capsules contain Avicel powder, which the research units consume 2 hours after delivery, every 6 hours to 24 hours.
Category
Placebo

3

Description
Control group: In this group, there will be no intervention on the mothers, and they received mefenamic acid capsules as needed (PRN) according to the routine of Ommolbanin Hospital. In this group, as in other groups, the number of capsules consumed and their after-pain measurement will be evaluated one hour after taking the medicine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ommolbanin Hospital
Full name of responsible person
Dr masoumeh Mirteimuri
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Sponsors / Funding sources

1

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Seyedeh Parvin Zabeti Asnad Astaneh

Position
Master Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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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
Not applicable

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