# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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

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Mashhad

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Razavi Khorasan

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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**
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## Sponsors / Funding sources

**1**

**Sponsor**
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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

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**Position**
Master Student

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Bachelor

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Midwifery

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## Person responsible for updating data

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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