

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of nigella sativa and Menstrogol ® and Mefenamic acid on postpartum pain in women with after-pain

Protocol summary

Study aim

Comparison of the effect of Nigella sativa and Menstrogol ® and Mefenamic acid on postpartum pain in women with after-pain

Design

Triple-blind randomized parallel clinical trial with two intervention and one control groups.

Settings and conduct

This three-blind study will be performed on women who refer to Valiasr Hospital in Birjand for delivery. Individuals will be assigned to three groups of placebo, monstrogel, and black seed if they meet the inclusion criteria with random blocking. Their postpartum pain will be measured with a numerical pain rating scale over 24 hours.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Satisfaction to participate in research Literacy for reading and writing Gestational age 37 to 42 weeks Spontaneous exit of pairs and curtains Having a moderate to severe back pain score Having a healthy and single baby Mother age 15-44 years Spontaneous vaginal delivery Iranian Start and perform breastfeeding successfully exclusion criteria: Having serious postpartum complications, not breastfeeding, smoking and using drugs, having medical illness, not taking drugs during labor, having grade 3 and 4 tears, taking painkillers during the last 4 hours, allergy to herbal medicines, Use of epidural and spinal anesthesia during labor, a history of cesarean section and abdominal surgery

Intervention groups

Intervention group 1: One 500 mg capsule of Nigella sativa every 6 hours for 24 hours about 2 hours after delivery Intervention group 2: One 500 mg capsule of Menstrogol every 6 hours for 24 hours about 2 hours after delivery Control group: One 250 mg capsule of mefenamic acid every 6 hours for 24 hours about 2 hours after delivery

Main outcome variables

postpartum pain and hemorrhage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200401046914N4**

Registration date: **2021-10-30, 1400/08/08**

Registration timing: **prospective**

Last update: **2021-10-30, 1400/08/08**

Update count: **0**

Registration date

2021-10-30, 1400/08/08

Registrant information

Name

Mahla Salarfard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3243 5793

Email address

salarfard.ma@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-11, 1400/08/20

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	type of intervention. The data analyst will not know the type of intervention. Therefore, the study will be conducted in a three-way blind.
Scientific title Comparison of the effect of nigella sativa and Menstrogol® and Mefenamic acid on postpartum pain in women with after-pain	Placebo Used
Public title Black seed and monstrogol and mefenamic acid on postpartum pain	Assignment Parallel
Purpose Treatment	Other design features
Inclusion/Exclusion criteria Inclusion criteria: Literacy for reading and writing Gestational age 37 to 42 weeks Spontaneous exit of pairs and curtains Having a moderate to severe back pain score Having a healthy and single baby Mother age 15-44 years Spontaneous vaginal delivery Iranian Start and perform breastfeeding successfully Satisfaction to participate in research Exclusion criteria: Having serious postpartum complications Lack of breastfeeding due to maternal and neonatal causes Smoking and drugs Having a medical illness Taking drugs during labor Having 3rd and 4th degree rupture Taking painkillers during the last 4 hours Allergy to herbal medicines use epidural and spinal anesthesia during labor Having history of cesarean section and abdominal surgery	Secondary Ids empty
Age From 15 years old to 44 years old	Ethics committees
Gender Female	1
Phase N/A	Ethics committee Name of ethics committee committee of Birjand University of Medical Sciences Street address Birjand University of Medical Sciences, Moalem Street City Birjand Province South Khorasan Postal code 9716813456
Groups that have been masked • Participant • Investigator • Data analyser	Approval date 2020-09-28, 1399/07/07 Ethics committee reference number IR.BUMS.REC.1399.286
Sample size Target sample size: 60	Health conditions studied
Randomization (investigator's opinion) Randomized	1
Randomization description Random allocation is done using three-membered blocks with a ratio of 1: 1: 1 with three members A = black seed capsule, B = monstrogel capsule C = mefenamic acid using block randomization method. To do this, first determine all possible combinations in the blocks (for example, "CBA, ABC, CAB) and then write them on the same pieces of paper and put them in a sealed envelope. The paper is randomly extracted and continues until the sample size is reached. The resulting sequence chain is used to assign participants to the groups.	Description of health condition studied postpartum pain ICD-10 code Z39 ICD-10 code description Encounter for maternal postpartum care and examination
Blinding (investigator's opinion) Triple blinded	Primary outcomes
Blinding description The capsule will be given to patients with a completely similar appearance and the form of the drugs will be the same. Therefore, the patient will not know the type of intervention. The data collector will not be aware of the	1 Description Intensity postpartum after-pain Timepoint Before and one hour after the first intervention, before and one hour after the second intervention, before and one hour after the third intervention, before and one hour after the fourth intervention. Method of measurement Numeric pain Rating scale
	2 Description

Postpartum hemorrhage
Timepoint
Before and after the intervention
Method of measurement
Higam bleeding measuring instrument

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One 500 mg capsule of Nigella sativa every 6 hours for 24 hours about 2 hours after delivery
Category
Treatment - Other

2

Description
Intervention group: One 500 mg capsule of Menstrogol every 6 hours for 24 hours about 2 hours after delivery
Category
Treatment - Other

3

Description
Control group: One 250 mg capsule of mefenamic acid every 6 hours for 24 hours about 2 hours after delivery
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital of Birjand
Full name of responsible person
Nahid Barati
Street address
Valiasr Hospital, Ghaffari St. Birjand City.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Dr Tooba Kazemi
Street address
Deputy of Research and Technology, Third Floor of Education and Research Building ,University of Medical Sciences, Birjand
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drtooba.kazemi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Nahid Barati
Position
Midwife
Latest degree
Master
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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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