

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 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 placenta and membranes 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

Scientific title

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

Public title

Black seed and monstrogol and mefenamic acid on postpartum pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Literacy for reading and writing Gestational age 37 to 42 weeks Spontaneous exit of placenta and membranes 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

Age

From **15 years** old to **44 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyst

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

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.

Blinding (investigator's opinion)

Triple blinded

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

type of intervention. The data analyst will not know the type of intervention. Therefore, the study will be conducted in a three-way blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

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

Approval date

2020-09-28, 1399/07/07

Ethics committee reference number

IR.BUMS.REC.1399.286

Health conditions studied

1

Description of health condition studied

postpartum pain

ICD-10 code

Z39

ICD-10 code description

Encounter for maternal postpartum care and examination

Primary outcomes

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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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**

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 updating data**Contact****Name of organization / entity**

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Position

Midwife

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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