

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study on the effect of wheat germ on postpartum after pain in women that referred to Mahdiah hospital in Tehran

Protocol summary

Study aim

Determination and Comparison of the Effect of wheat germ on postpartum pain

Design

Clinical trials with control group, with parallel groups, double blind, randomized

Settings and conduct

This study is a randomized double blind control trial with Placebo to determine the effect of the wheat germ capsule on the After pain in women referring to Mahdiah Hospital in Tehran in 1397. If samples have a score of 4 or more, they will enter the study. The sample size is 90 person, each group consisting of 45 person. In the case group, two hours after delivery a wheat germ capsule will be given every six hours for 48 hours and in the control group, two hours after delivery a placebo capsule will be given every six hours for 48 hours and one hour after each intervention, the severity of pain is recorded by the pain ruler as a self-report of the samples and if the pain does not relieve, Mefnamic Acid capsule will be given and their number will be recorded

Participants/Inclusion and exclusion criteria

Inclusion criteria : Vaginal Delivery, Be Complained of Moderate or Severe pain after Delivery, No Maternal History of Herbal Drugs Allergy, Mother age between 18-35 years, Deliver a Singleton and Healthy Baby. Exclusion criteria: Maternal History of Herbal Drugs Allergy, Maternal History of Chronic Disease, The mother has no history of cesarean section or abdominal or pelvic surgery

Intervention groups

In the case group, two hours after delivery one wheat germ capsule containing 500 mg of powder will be given every six hours for 48 hours and in the control group, two hours after delivery one placebo capsule containing 500 mg of starch will be given every six hours for 48 hours. In both groups, one hour after each intervention, if the pain does not relieve, one Mefnamic Acid 250 mg capsule will be given as routine treatment and their number will

be recorded.

Main outcome variables

Severity of after pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200211046452N1**

Registration date: **2020-04-01, 1399/01/13**

Registration timing: **retrospective**

Last update: **2020-04-01, 1399/01/13**

Update count: **0**

Registration date

2020-04-01, 1399/01/13

Registrant information

Name

Samira Mehravar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3843 4085

Email address

samiramehravar@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

2019-10-01, 1398/07/09

Actual recruitment end date

2020-01-04, 1398/10/14
Trial completion date
2020-01-06, 1398/10/16

Scientific title
Study on the effect of wheat germ on postpartum after pain in women that referred to Mahdiah hospital in Tehran

Public title
Study on the effect of wheat germ on postpartum after pain

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Be Iranian Speak Persian Lives with her husband The mother had vaginal delivery Single and healthy baby Gestational age between 37 to 42 weeks The mother has the ability to breast-feed The baby has the ability to breast-feed The mother is satisfied to participate in the study The mother suffers from moderate to severe postpartum pain Delivery whit out devices The mother has no history of cesarean section and abdominal and pelvic surgery Not used of epidural or spinal anesthesia Non-smoking and drug abuse The mother does not have a chronic disease (Hypertension, diabetes, heart disease) Has no history of allergy to wheat germ or other herbal drugs
Exclusion criteria:
Use other herbal or chemical drugs except Mefenamic Acid during the study to relieve pain The mother is suffering from serious complications after delivery (postpartum bleeding, temperature over 39 ° C, blood pressure higher than 140/90) Breast feeding may not be possible for maternal or neonatal reasons The mother is not willing to continue her participation in the study for any reason Sensitivity to wheat germ happen during study

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Actual sample size reached: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method and description of each method: In the custody In randomization unit: Individual
Randomization tool: Random number function, opaque and closed envelopes How to create random sequence: Generate random number function in Excel software.

Blinding (investigator's opinion)

Double blinded

Blinding description
In order to blind the allocation, the pills will be divided into the opaque A and B packets and numbered by the pharmaceutical consultant .Participant, researcher and outcome checker will be unaware of the type of intervention

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Of Shahid Beheshti University Of Medical Sciences

Street address
Nursing And Midwifery College Of Shahid Beheshti University Of Medical Sciences, In Front Of Shahid Rajaei Heart Hospital, Niayesh Intersection, Valiasr Avenue

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2019-02-25, 1397/12/06

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1397.262

Health conditions studied

1

Description of health condition studied
After Pain

ICD-10 code
O85-O92

ICD-10 code description
Complications predominantly related to the puerperium

Primary outcomes

1

Description
Severity of after pain

Timepoint
Before intervention and 1 hour after it

Method of measurement
The Mc Gill Pain Ruler

Secondary outcomes

1

Description

Side effects of the drug

Timepoint

After the intervention

Method of measurement

Side Effects Questionnaire

Intervention groups

1

Description

Intervention group: Two hours after delivery one wheat germ capsule containing 500 mg of powder will be given every six hours for 48 hours and one hour after each intervention, if the pain does not relief, one Mefnamic Acid 250 mg capsule will be given as routine treatment and their number will be recorded.

Category

Treatment - Drugs

2

Description

Control group: Two hours after delivery one placebo capsule containing 500 mg of starch will be given every six hours for 48 hours and one hour after each intervention, if the pain does not relief, one Mefnamic Acid 250 mg capsule will be given as routine treatment and their number will be recorded.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh Hospital

Full name of responsible person

Zahra Esmi

Street address

Shishe Gar khaneh Alley, Fadaian Islam Ave, Shoosh Sq, Tehran, Iran

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Email

mahdiyeh_hospital@sbm.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sedighe Amir Ali Akbari

Position

Educator

Latest degree

Ph.D.

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

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