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 Mahdieh 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 Mahdieh Hospital in Tehran in 1397. If samples have a score of 4 or more, they will enter the study.The samples 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 relief,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 relief,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 Mahdieh 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 Rajaee 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
City
Tehran
Province
Tehran
Postal code
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mahdiyeh_hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Nursing And Midwifery College Of Shahid Beheshti University Of Medical Sciences, In Front Of Shahid Rajaee Heart Hospital, NiayeshIntersection, Valiasr Avenue
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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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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
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