Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of mixed ethanolic extract (Black seed and Dill seeds) on some parameters of postpartum maternal physical health compared with mefnamic acid

Protocol summary

Study aim
Determination of the effect of mixed ethanolic extract (Black seed and Dill seeds) compared with mefenamic acid on some parameters of postpartum maternal and neonatal physical health

Design
Two arm parallel group randomised clinical trial with double-blinded postoperative care

Settings and conduct
Female with term pregnant referred to Emam Sajad hospital divided into two groups of mixed ethanolic extract (Black seed and Dill seeds) and mefenamic acid for 3 days. Patient and nurse do not know about kind of medicine.

Participants/Inclusion and exclusion criteria
Female with term pregnancy and stable hemodynamic status

Intervention groups
In intervention group A: The black seeds and dill seeds are each washed separately and after drying in the shade, the plant will be milled, and extracted with 70% ethanol for 48 hours by maceration technique. The hydroalcoholic solution is then separated by filter paper from the plant particles and the remaining ethanol is collected by a rotary machine. The residue of the extract is kept at 37 ° C for evaporation. Finally, the dried extract is stored at 20 ° C for testing in the clinical laboratory. The selective dose of the dried extract in the combined capsule in the present study was 500 mg of black seed and 400 mg of dill daily. It should be noted that the relevant dose has been selected after studying the previous articles, evaluating human safety and the opinion of the consultant professor. In intervention group B: Mefenamic acid will be completely similar in appearance to group A and will be administered in the same manner. Mefenamic acid will be administered 250 mg every six hours during the first three days after delivery.

Main outcome variables
Hemorrhage, pain and breast feeeding after delivery

General information

Reason for update

Acronym
PPH

IRCT registration information
IRCT registration number: **IRCT20200214046492N1**
Registration date: **2020-04-01, 1399/01/13**
Registration timing: **prospective**

Last update: **2020-04-01, 1399/01/13**
Update count: **0**

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

Registrant information

Name
Elaheh Foroutani fard

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3229 3163

Email address
vestal2475@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-03, 1399/01/15

Expected recruitment end date
2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of mixed ethanolic extract (Black seed and Dill seeds) on some parameters of postpartum maternal physical health compared with mefnamic acid

Public title

Evaluation of the effect of mixed ethanolic extract (Black seed and Dill seeds) on pain and post partum hemorrage

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestation age 38-42 week Singletone pregnancy NVD Mother age 15-44 iranian spontaneous placental remove no previous surgery no spinal or opium HB>8 no ROM >12 no opium addiction no sensetive to herbal no percipitate labor or prolonge labor BMI 18/5-29/5 Fetal weight 2500-4000 no disease in mother no operative vaginal delivery no 3,4 degree laceration no use warfarin,banzodiazepin,ASA,Alcohol,heparin

Exclusion criteria:

no breast feeding no cooprative patient use another herbal no sensetive to herbal severe dissease in mother and neonate

Age

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

Gender

Female

Phase

1-2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

The study units will be divided into groups A and B on the basis of random allocation by computer random generation. The appearance of the drug and placebo will be quite similar. The participants and the researcher are completely unaware of the drugs, but the pharmacist is aware (double-blinded).

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and nurse do not know kind of medicine. All patient was taken the same shape medicine.

Placebo

Not used

Assignment

Parallel

Other design features

Use 2 ethanol herbal in one capsule

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Faculty of medicine, Medical campus, Next to Imam Sajjad Hospital, Shahid Dr. Ghorban Ali Jalil Ave

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

75919-94799

Approval date

2020-02-13, 1398/11/24

Ethics committee reference number

IR.YUMS.REC.1398.153

Health conditions studied

1

Description of health condition studied

Postpartum hemorrhage and pain

ICD-10 code

O72.1

ICD-10 code description

Other immediate postpartum hemorrhage

Primary outcomes

1

Description

Postpartum hemorrhage

Timepoint

Before study then first hour till 6hrs then till 3days

Method of measurement

Iranian GYN and OB protocol

2

Description

Pain

Timepoint

Before study then first hour till 6hrs then till 3days

Method of measurement

Visual Analogue Scale Score

Secondary outcomes

1

Description

Breast feeding

Timepoint

Three days in the time of intervention then 2 weeks later

Method of measurement

Urination and defication of neonate

2

Description

Liver function

Timepoint

After intervention

Method of measurement

Blood test

3

Description

Complete Blood Count

Timepoint

After intervention

Method of measurement

Blood test

4

Description

Renal function

Timepoint

After intervention

Method of measurement

Blood test

5

Description

Sodium, Potassium

Timepoint

After intervention

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group A: The black seeds and dill seeds are each washed separately and after drying in the shade, the plant will be milled, and extracted with 70% ethanol for 48 hours by maceration technique. The hydroalcoholic solution is then separated by filter paper from the plant particles and the remaining ethanol is collected by a rotary machine. The residue of the extract is kept at 37 ° C for evaporation. Finally, the dried extract is stored at 20 ° C for testing in the clinical laboratory. The selective dose of the dried extract in the combined capsule in the present study was 500 mg of black seed and 400 mg of dill daily. It should be noted that the relevant dose has been selected after studying the previous articles, evaluating human safety and the opinion of the consultant professor.

Category

Treatment - Drugs

2

Description

Intervention group B: Mefenamic acid will be completely similar in appearance to group A and will be administered in the same manner. Mefenamic acid will be administered 250 mg every six hours during the first three days after delivery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Sajad Hospital

Full name of responsible person

Zahra Zare

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Emam Sajad Hospital, Saheli Str

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Seyed Ali Mosavizadeh

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Vice chancellor of research, Kohgiluyeh and Boyer-Ahmad University of Medical Sciences, Shahid Motahari Blvd

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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
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Elaheh Foroutanifard
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Resident
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information about main outcomes of the study
When the data will become available and for how long
Six months after publishing the results
To whom data/document is available
Researchers in universities and scientific and research centers
Under which criteria data/document could be used
In order to improve the control of postpartum hemorrhage and pain, and subsequent researches, and with the permission of the authors

From where data/document is obtainable

Department of Obstetrics and Gynecology of Yasuj university of medical sciences

What processes are involved for a request to access data/document

Sending the request in writing or by email to the authors

Comments