Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparative study on the effects of herbal capsule of Anise and Mefenamic acid on postpartum after pain on women that referred to Shohada Hospital of Ghochan

Protocol summary

Summary

After pain is one of the complications occurring during postpartum, this requires an appropriate analgesic to relieve the pain. The current study was designed to study and compare the analgesic effects of Anise and Mefenamic acid capsule on postpartum pain. This study was a randomized double-blind controlled clinical trial in which pregnant mothers having normal vaginal delivery and suffering from postpartum pain were studied. Ninety six volunteer pregnant women were selected using Random-number table and entered into two study groups of Anise (intervention group) and Mefenamic acid (control group) oral capsules. Using the Numerical Analogue Scale, afterpain was determined during the first 1 hours after delivery and patient received drugs if a pain score 4 or more than 4 was expressed by patients. These women were administered 4 doses of during 24 hours (every 6 hours). Severity of pain were measured and recorded before and 1 hour after medication.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512203860N21**
Registration date: **2016-02-07, 1394/11/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-07, 1394/11/18

Registrant information

Name

Gity Ozgoli

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

gozgoli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effects of herbal capsule of Anise and Mefenamic acid on postpartum after pain on women that referred to Shohada Hospital of Ghochan

Public title

A comparative study on the effects of herbal capsule of Anise and Mefenamic acid on postpartum after pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Iranian; speak the Persian language; lives with his wife; they had normal vaginal delivery; single pregnancy with healthy baby; Gestational age between 37 to 42 weeks; the mother have the ability to

breast-feeding; The baby can be feeding; mother for research is satisfied; women who suffer from postpartum pain; severity of postpartum pain is moderate to severe (scored more than 4 degree based on Numerical scale and need to use narcotics); normal vaginal delivery without devices (Vacuum, forceps); the mother does not have cesarean section and abdominal surgery history; Not used of epidural or spinal anesthesia; Non-smoking and drug abuse; the mother does not have a chronic disease (Hypertension, diabetes, heart disease, infectious diseases); No have allergy to Anise and other herbal drug; Exclusion criteria: herbal medicines or chemicals are used for pain relief during the study; the mother is suffering from serious complications after delivery (postpartum bleeding, temperature over 39 ° C, blood pressure higher than 140/90); continuation of breastfeeding to mother or baby is not possible causes; mother, for whatever reason are not willing to continue to participate in the study; foods containing spices are used during study

Age
From **20 years** old to **30 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This research is a double-blind study in which researcher and patients are not aware about prescribed capsules. Capsules are put in the bar coded packets and given to the patients randomly.

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
School of Nursing and Midwifery, Niayesh Highway, Valiasr St, Tehran, Iran

City
Tehran

Postal code

Approval date
2013-09-02, 1392/06/11

Ethics committee reference number
11635

Health conditions studied

1

Description of health condition studied
postpartum after pain

ICD-10 code
Z39

ICD-10 code description
Postpartum care and examination

Primary outcomes

1

Description
Severity of pain

Timepoint
Before intervention, one hour after delivery then every 6 hours for 24 hours

Method of measurement
Numerical Analogue Scale

Secondary outcomes

1

Description
The number of additional analgesic

Timepoint
one hour after delivery then every 6 hours for 24 hours

Method of measurement
Questionnaire

Intervention groups

1

Description
control group:The samples were given a Mefenamic Acid oral capsule 250mg ,one hour after delivery then every 6 hours for 24 hours.

Category
Treatment - Drugs

2

Description
Intervention group: The samples were given a Anise oral capsule containing 60 mg of dried extracts of anise (produced in Shahid Beheshti pharmacy faculty), one hour after delivery then every 6 hours for 24 hours.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohada Hospital

Full name of responsible person
Asiyeh Khodadadi

Street address
Shohada Hospital, Emam khomeini Street, Ghochan, Iran

City
Ghochan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
vice chancellor for research of Shahid Beheshti University of Medical Sciences(SBUMS)

Full name of responsible person
Dr.Afshin Zarghi

Street address
7th Floor, 2nd SBUMS Bldg. ,Next to Ayatollah Taleghani Hospital, Evin , Tehran, Iran.

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
vice chancellor for research of Shahid Beheshti University of Medical Sciences(SBUMS)

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Gity Ozgoli

Position
PHD of Reproductive Health

Other areas of specialty/work

Street address
School of Nursing and Midwifery, Niayesh Highway, Valiasr St. Tehran, Iran.

City
Tehran

Postal code

Phone
+98 21 8820 2512

Fax

Email
g.ozgoli@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Gity Ozgoli

Position
PHD of Reproductive Health

Other areas of specialty/work

Street address
School of Nursing and Midwifery, Niayesh Highway, Valiasr St, Tehran, Iran

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Tehran

Postal code

Phone
+98 21 8820 2512

Fax

Email
g.ozgoli@gmail.com

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty