

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

A comparative study on the effect of herbal capsules Melisa and Mefnamic acid on postpartum after pain on women that referred to Askarie hospitals of Isfahan in 2016

Protocol summary

Summary

This study was a randomized double-blind controlled clinical trial in which pregnant mothers having normal vaginal delivery and suffering from postpartum. In this study were compared the analgesic effects of Melisa and Mefenamic acid capsule on postpartum pain. 70 volunteer pregnant women were selected using Random-number table and entered into two study groups of Melisa (intervention group) and Mefenamic acid (control group) oral capsules. Using the Numerical Analogue Scale, after pain was determined during the first 2 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: **IRCT201608023860N25**

Registration date: **2016-12-28, 1395/10/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-28, 1395/10/08

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 International Branch of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of herbal capsules Melisa and Mefnamic acid on postpartum after pain on women that referred to Askarie hospitals of Isfahan in 2016

Public title

A comparative study on the effects of herbal capsule of Melisa 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 Melisa and other herbal drug. Exclusion criteria: 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.

Age

From **19 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

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 The International Branch of Shahid Beheshti University Of Medical Sciences & Hea

Street address

Shahid Abaspor st, Tavanir st, Hemmat bridge

City

Tehran

Postal code

Approval date

2016-04-17, 1395/01/29

Ethics committee reference number

IR.SBMU.RAM.REC1395.71

Health conditions studied

1

Description of health condition studied

After paine

ICD-10 code

z39

ICD-10 code description

postpartum care and examination

Primary outcomes

1

Description

seventry of pain

Timepoint

Before intervention - 2 hours after delivery - then every 6 hours for 24 hours

Method of measurement

Numerical Analogus Scale

Secondary outcomes

1

Description

the Number of additional analgesic

Timepoint

2hours after delivery then every 6 hours numerical Analogus SCALE

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: The samples were given a Melisa oral capsule containing 150 mg of dried extracts of Melisa (produced in goldaro company), two hour after delivery then every 6 hours for 24 hours.

Category

Treatment - Drugs

2

Description

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

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Askarieh Hospital
Full name of responsible person
Mojgan Naderi
Street address
Askarieh Hospital, Soroush st, Esfahan
City
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1985717443
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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. Mahrokh Dolatian
Street address
School of Nursing and Midwifery, Niayesh Highway,
Valiasr St, 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
School of Nursing and Midwifery of 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,
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City

Person responsible for scientific inquiries

Contact

Name of organization / entity
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gozgoli@yahoo.com
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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