

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

A comparative study on the effects of Menstrogol ® and Mefenamic acid on postpartum pain

Protocol summary

Summary

After pain is a complication occurring during postpartum, which requires an appropriate analgesic to relieve the pain. The current study was designed to study and compare the analgesic effects of menstrogol and mefenamic acid on post-partum pain. This study was a randomized single-blinded controlled clinical trial in which pregnant mothers, having normal vaginal delivery and suffering from post partum pain, were studied. Volunteer pregnant women were randomly entered into two study groups of menstrogol (containing 500 mg of dried extracts of celery, saffron and anise) and mefenamic acid (250 mg) oral capsules. Using the visual analogue scale (VAS), After pain was determined during the first 2 hours after delivery and patients received the study drugs if a pain score ≥ 4 was expressed by patients. These women were administered 4-3 doses of study drugs per day (every 6-8 hours). Severity and duration of pain were measured and recorded before and 1 hour after dosage administration.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201228801N1**

Registration date: **2012-04-21, 1391/02/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-04-21, 1391/02/02

Registrant information

Name

Masoumeh Simbar

Name of organization / entity

Shahid Beheshti University for Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8820 2517

Email address

msimbar@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2011-04-07, 1390/01/18

Expected recruitment end date

2012-02-07, 1390/11/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effects of Menstrogol ® and Mefenamic acid on postpartum pain

Public title

A comparative study on the effects of Menstrogol ® and Mefenamic acid on postpartum pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Participants were 17-35 years old women; primary or multiparous women who suffer from postpartum pain (scored more than 4 degree based on Visual scale and need to use narcotics); they had normal vaginal delivery; they had not any complication during childbirth, such as using vacuum or forceps, perineal laceration, prolonged labor, Neonate weight more than 3500g, birth of twins or more than one fetuses, using

analgesics in previous 2 weeks; they had alive childbirth; infant without malformation; not using any drug in the ward (synthetics or herbal); they were in their 38-40 weeks for gestational age; they had no sensitivity to herbal medicines. Exclusion criteria: Participants who need to surgery or stronger analgesics, or experience the side effects.

Age

From **17 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Tavanir ave., After Mirdamad., Vali asr ave.

City

Tehran

Postal code

Approval date

2010-12-20, 1389/09/29

Ethics committee reference number

4336/116

Health conditions studied

1

Description of health condition studied

postpartum pain

ICD-10 code

O26

ICD-10 code description

Maternal care for other conditions predominantly related to pregnancy

Primary outcomes

1

Description

severity of pain

Timepoint

1 hour after usage of drug

Method of measurement

visual analogue scale

Secondary outcomes

1

Description

duration of pain

Timepoint

1 hour after usage of drug

Method of measurement

upon hour and minute

2

Description

Side effects

Timepoint

1 hour after usage of drug

Method of measurement

Patients' side effects based on their statements

Intervention groups

1

Description

Group 2: One hour after childbirth, they were given a capsule of Mefenamic acid to relief their pain. The participants were given another dose of the drugs if their pain relapsed. This process was repeated to 4 times.

Category

Treatment - Drugs

2

Description

Group 1: One hour after childbirth, they were given a capsule of Menstrogl to relief their pain. The participants were given another dose of the drug if their pain relapsed. This process was repeated to 4 times.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Zahra treatment and education center

Full name of responsible person

Street address

Ememzadeh ebrahim ave.

City

Ghom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Goldaru Company

Full name of responsible person

Dr. Fariborz Moattar

Street address

Esfahan Goldaru Company

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Goldaru Company

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Rahmati

Street address

Deputy of resarch.,Shahid Beheshti University of Medical Sciences, Velenjak

City

Tehran

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

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

Dr. Masoumeh Simbar

Position

Associate Professor/ PhD of reproductive health

Other areas of specialty/work

Street address

Department of Reproductive Health and Midwifery, Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences (3th floor, Deputy of research), Vali-Asr Avenue, Cross of Vali-Asr and Neiaiesh Highway, Opposite to Rajae Heart Hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Masoumeh Simbar

Position

phd of reproductive health

Other areas of specialty/work

Street address

Department of Reproductive Health and Midwifery, Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences (3th floor, Deputy of research), Vali-Asr Avenue, Cross of Vali-Asr and Neiaiesh Highway, Opposite to Rajae Heart Hospital

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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