

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of the effect of Fennel capsules and Ibuprofen on postpartum after pain in multiparous women admitted in postpartum ward of Sanandaj Beasat hospital

Protocol summary

Summary

The purpose of the study is investigating the effect of the fennel capsules and ibuprofen tablets on the amount of labor's after pain in multiparous women admitted in postpartum ward of the Besat Hospital in Sanandaj. The kind of the study is single blind clinical trail, this means that the number of 70 patients with vaginal delivery who have got the number of 4 or more for their pain -in that case of not having an instrumental delivery, not having the tear of 3 or 4 degrees and unsatisfactorily from the cooperation -will be studied. we randomly will putting up the samples on two groups means 35 persons who will be studied with fennel capsules or ibuprofen tablets on each one of groups. demographic characteristics and obstetric history of the patients will be recorded on the information forms, then we will measure the intensity of pain every time before, after and 1 hour after the intervention, we do that for 4 times with the duration of every 6 times until 24 hours using VAS (Vaginal Analogue Scale), then we will record it in the information forms .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100930238N1**

Registration date: **2017-02-10, 1395/11/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2017-01-24, 1395/11/05

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of Fennel capsules and Ibuprofen on postpartum after pain in multiparous women admitted in postpartum ward of Sanandaj Beasat hospital

Public title

Fennel effect on pain after childbirth

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: vaginal delivery; The term gestational age (40-37 weeks); live births; singleton; fetal weight 4000-2500 g;The lack of specific diseases such as ulcers or gastrointestinal bleeding or known cardiovascular

disease; higher pain score of 4 and Exclusion criteria: severe bleeding after childbirth; Perform evacuating corpus luteum or manual removal of placenta; Use the tools (vacuum, forceps),having perineal tear grade 3 and 4; The labor long and hard;sensitivity to fennel; In case of dissatisfaction with the continued cooperation in the study for any reason and at any stage of the research will be withdrawn.

Age

From **17 years** old to **50 years** old

Gender

Female

Phase

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)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kurdistan University of Medical Sciences

Street address

Ground Floor of Kurdistan University of Medical Sciences, Paasdaaran St Sanandaj, Kurdistan, Iran

City

Sanandaj

Postal code

6617713446

Approval date

2016-06-13, 1395/03/24

Ethics committee reference number

MUK.REC.1395.85

Health conditions studied

1

Description of health condition studied

post partum after pain

ICD-10 code

O00,O99,O8

ICD-10 code description

Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

post partum after pains

Timepoint

Every 6 hours up to 24 hours before and hour after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group fennel capsules 30 mg orally every 6 hours for 24 hours after delivery

Category

Treatment - Drugs

2

Description

In the control group Ibuprofen 200 mg orally every 6 hours for 24 hours after delivery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Leila Hasheminasab

Street address

Department for Midwifery, Kurdistan University of Medical Sciences, Sanandaj, Kurdistan, Iran

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University Of Medical Sciences

Full name of responsible person

Farzin Rezaei

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Kurdistan University Of Medical Sciences
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 Sanandaj
Grant name
 1395.85
Grant code / Reference number
 25000000
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Kurdistan University Of Medical Sciences
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

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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