Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A double blind, cross over, placebo controlled study of standardized hydro-alcoholic extract of stachys lavandulifolia on primary dysmenorrhea symptoms

Protocol summary

Summary

Primary dysmenorrhea is one of the most frequent gynecological disorders in young women. As reported in literatures it has many economical and social impacts. According to past pharmacological studies it was confirmed that components of stachys may have some anxiolytic, anti-inflammatory, analgesic and spasmolytic effects. After preparation of standardized capsule formulation of hydro alcoholic extract of stachys lavandulifollia base on thymol, 30 women aged 18 to 45 years with diagnosis of primary dysmenorrhea were enrolled in this double blind randomized cross-over clinical trial. After control cycle and consumption of mefenamic acid in one cycle, each patient received either herbal capsules or placebo randomly. In next cycle placebo and herbal capsules were switched in a cross over manner. At the end of each cycle intensity of pain was evaluated by McGill pain questionnaire and visual analogue scale (VAS). Finally improvement rate and consumption of mefenamic acid capsules and probable side effects of drug were assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904133106N2**
Registration date: **2010-12-19, 1389/09/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-12-19, 1389/09/28

Registrant information

Name

Farshad Hashemian

Name of organization / entity

Pharmaceutical Sciences Branch, Islamic Azad University (IAU)

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Recruitment status

Recruitment complete

Funding source

1- Pharmaceutical Sciences branch of Islamic Azad University, 2- investigators financial sources

Expected recruitment start date

2010-02-01, 1388/11/12

Expected recruitment end date

2013-06-01, 1392/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A double blind, cross over, placebo controlled study of standardized hydro-alcoholic extract of stachys lavandulifolia on primary dysmenorrhea symptoms

Public title

The effect of stachys lavandulifolia extract on the symptoms of primary dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : 1-age of 18-45 years, 2- diagnosis of

primary dysmenorrheal, 3- existence of dysmenorrhrea in most of cycles. Exclusion criteria: 1-pregnancy, 2-lactation, 3-abnormal vaginal bleeding, 4-moderate to sever menorrhagia, 5-BMI more than 30, 6-OCP and other hormonal drugs consumption.

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Pharmaceutical science branch of Islamic azad university

Street address
No.99, Yakhchal street, Dr. Shariati Avenue

City
Tehran

Postal code

Approval date
2010-07-05, 1389/04/14

Ethics committee reference number
4113

Health conditions studied

1

Description of health condition studied
Primary dysmenorrhea

ICD-10 code
N94.4

ICD-10 code description
Primary dysmenorrhea

Primary outcomes

1

Description
severity of pain

Timepoint
at the end each cycle up to three cycles

Method of measurement
macgill pain questionnaire

2

Description
severity of pain

Timepoint
at the end each cycle up to three cycles

Method of measurement
visual analogue scale (VAS)

Secondary outcomes

1

Description
side effects

Timepoint
at the end each cycle up to three cycles

Method of measurement
questionnaire

Intervention groups

1

Description
Placebo: In case of existence of dysmenorrheal pain, 24 hours before initiation of approximate cycle time till 48 hours after, patients should take 1 capsule and repeat it each 4-6 hours if needed.

Category
Placebo

2

Description
Herbal capsule: In case of existence of dysmenorrheal pain, 24 hours before initiation of approximate cycle time till 48 hours after, patients should take 1 capsule and repeat it each 4-6 hours if needed.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Buali hospital

Full name of responsible person
Fatemeh Mohammadyari

Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pharmaceutical science branch of Islamic Azad university
Full name of responsible person
Dr. Orkideh Ghorban dadras
Street address
No.99, Yakhchal street, Dr. Shariati Avenue
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Pharmaceutical science branch of Islamic Azad university
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Pharmaceutical science branch of Islamic azad university
Full name of responsible person
Dr. Farshad Hashemian
Position
Assistant professor / Head of Department
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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