

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of St John's Wort on severity, frequency and duration of hot flashes in peri and postmenopausal women

Protocol summary

Deputy for Research of Shiraz University of Medical Sciences

Summary

Objective: To compare the efficacy and safety of St John's wort with placebo in outpatients with hot flashes. Methods: 100 menopausal women participated in a clinical trial conducted in several academic medical centers in Shiraz-Iran. Patients were treated with St. John's wort extract or placebo for 8 weeks. Climacteric complaints were evaluated using Kupperman Index at two follow up visits.

Expected recruitment start date

2008-11-09, 1387/08/19

Expected recruitment end date

2009-03-09, 1387/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138710241548N1**

Registration date: **2009-09-09, 1388/06/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-09-09, 1388/06/18

Registrant information

Name

Khadijeh Abdali

Name of organization / entity

Fatemeh college of nursing and midwifery, Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1647 4255

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Recruitment status

Recruitment complete

Funding source

Scientific title

The effect of St John's Wort on severity, frequency and duration of hot flashes in peri and postmenopausal women

Public title

Evaluation of the effect of an herbal medication on severity, frequency and duration of hot flashes in menopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (1) natural perimenopuse (3-11 months of amenorrhea or increased menstrual irregularity if still cycling) or postmenopause (12 or more months of amenorrhea) (2) untreated complaints for at least 2 months, (3) no history of cancer, (4) moderate to severe hot flashes happening at least once a day, (5) lack of illnesses creating hot flash-like symptoms, (6) presenting the serum level of FSH more than 40 mlu/ml. Exclusion criteria: (1) treatment with sexual hormones, nonhormonal climacteric drugs, or any treatment to alleviate climacteric symptoms in the last 12 weeks before study entry, (2) treatment with chemical or plant-derived medicines in the last 12 weeks before study entry, (3) bilateral oophorectomy, and (4) severe diseases (e.g., of the heart, liver, kidney, alimentary

system, or metabolic diseases) or abnormal thyroid-stimulating hormone value that could mimic climacteric complaints or the actual or expected treatment or that could interfere with the study objectives.

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Medical Research Ethics Committee of Shiraz
University of Medical Sciences

Street address

Zand sq.

City

Shiraz

Postal code

Approval date

empty

Ethics committee reference number

87-4288

Health conditions studied

1

Description of health condition studied

Hot flashes in peri and postmenopausal women

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

decrease of the severity, frequency and duration of hot flashes

Timepoint

one month

Method of measurement

Kupperman Index

Secondary outcomes

empty

Intervention groups

1

Description

placebo: 20 drops, three times daily for 2 months

Category

Placebo

2

Description

Hypiran: 20 drops, three times daily for 2 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

outpatient academic medical center of Zeynabiyeh
Hospital

Full name of responsible person

Street address

City

Shiraz

2

Recruitment center

Name of recruitment center

outpatient academic medical center of Hafez Hospital

Full name of responsible person

Street address

City

Shiraz

3

Recruitment center

Name of recruitment center

outpatient academic medical center of Shahid Faghihi
Hospital

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research of Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hosein Dabbagh Manesh

Street address

Zand st.

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research of Shiraz 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

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Fatemeh College of nursing and midwifery

Full name of responsible person

Khadijeh Abdali

Position

Master's degree in midwifery, faculty member

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Khadijeh Abdali

Position

Other areas of specialty/work

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Phone

Fax

Email

Web page address

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