Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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.

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

Deputy for Research of Shiraz University of Medical Sciences

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

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
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Full name of responsible person
Khadijeh Abdali
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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