

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of Hypericum on menopause early symptom

Protocol summary

Summary

(1) objective: The effect of Hypericum on menopause early symptom.(2) design: This study is a randomized clinical trial, double-blind, placebo-controlled that will be conducted using random sampling.(3) Setting and conduct:researcher will be selected 80 person after interviews and put them in intervention and control groups from among postmenopausal women referred to health centers the . On the first meet will be completed the demographic information and Kupperman Index questionnaire for samples.Intervention and control groups meet every second week for 8 weeks and to be completed and evaluated Kupperman Index questionnaire for them. Participants main of Inclusion and exclusion criteria: main inclusion criteria: age 60-45 years; amenorrhea for at least 12 months, there are at least two menopause of symptom, according to Kupperman index.main exclusion criteria: Higher body mass index of 30; abnormal menopause, known systemic diseases, sexual hormones.(5) Interventions: to each of the women in the intervention group will be given perforan tablets (330 mg) three times a day and will be given a placebo control group.(6) The main outcome variables: hot flashes, night sweats, insomnia, nervousness, depression, fatigue, headache, frequent urination and bladder pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012510687N4**
Registration date: **2017-02-26, 1395/12/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-26, 1395/12/08

Registrant information

Name

Somaye Ansari

Name of organization / entity

School of Nursing and Midwifery, JundiShapur
University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ground floor, Ahvaz Junishapur University of Medical
Science and Health Services of Department Research
Development and Technological, Academic city, Ahvaz

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Hypericum on menopause early symptom

Public title

The effect of Hypericum on menopause early symptom

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included: age 60-45 years; amenorrhea for at least 12 months; there are at least two menopause of symptom according to Kupperman index; having read and write. Exclusion criteria: women with amenorrhea

due to the abnormal menopause; hysterectomy, oophorectomy and radiation therapy; known systemic diseases such as endocrine disorders (thyrotoxicosis); dietary intake of phytoestrogens and the whole regime; having known physical and mental diseases; consumption sexual hormones; sensitivity to herbal drugs; women athletes; consumption antidepressants drug; herbal medicines; higher body mass index³⁰

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Ahvaz JundiShapur University of Medical Sciences and Health Services of Ethics Committee

Street address

Ahvaz Jundishapur University of Medical Science and Health Services, Golestan BLV, Ahvaz

City

Ahvaz

Postal code

61357-15794

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

8-20-4411-پ

Health conditions studied**1****Description of health condition studied**

menopause early symptom

ICD-10 code

N95.3

ICD-10 code description

States associated with artificial menopause

Primary outcomes**1****Description**

menopause early symptom

Timepoint

Before intervention, 2 weeks after intervention, 4 weeks after the intervention, 6 weeks after the intervention, 8 week after intervention

Method of measurement

kupperman index questionnaire

Secondary outcomes**1****Description**

Side effects of Hypericum

Timepoint

2 week after intervention, 4 week after intervention, 6 week after intervention, 8 week after intervention

Method of measurement

Questionnaire

Intervention groups**1****Description**

Perforating tablet contains 330 mg hypericin 3 times daily in intervention group will be administered for 8 weeks. Information collected through interviews and questionnaires individual characteristics and symptoms will be collected Kupperman index. Kupperman Index is based on nine symptoms of menopause include hot flashes in, night sweats, insomnia, nervousness, depression, fatigue, headache, frequent urination and bladder pain. Kupperman questionnaire will be completed for participant before the study and at weeks 2, 4, 6 and 8 weeks after the start of the intervention.

Category

Treatment - Drugs

2**Description**

In controlled group will be placebo for three times a day for 8 weeks. Kupperman questionnaire will be completed for participant before the study and at weeks 2, 4, 6 and 8 weeks after the start of the intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz East Health Center

Full name of responsible person

Shahnaz Najar

Street address

Ahvaz East Health Center, facing the Haftetir Park,
Rastegari Street, Ayatollah Behbahani highway,
Ahvaz

City

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2

Recruitment center

Name of recruitment center

Ahvaz west Health Center

Full name of responsible person

Shahnaz Najar

Street address

Ahvaz west Health Center, Kiyababad, Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Science

Full name of responsible person

Doctor Behzad Sharif Makhmalzadeh

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Ground floor, Ahvaz Junishapur University of Medical
Science and Health Services of Department Research
Development and Technological, Academic city,
Ahvaz

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Science

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

Name of organization / entity

School of Nursing and Midwifery, JundiShapur
University of Medical Sciences and Health Services

Full name of responsible person

Somaye Ansari

Position

Masters of Midwifery

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

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Full name of responsible person

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Master of Midwifery/Academic Board

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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