Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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, ther 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
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School of Nursing and Midwifery, JundiShapur University of Medical Sciences and Health Services
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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 assosiated with artificial menopaus

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 interventionention

Method of measurement
kupperman index questionarie

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
Questionarie

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 Eeast Health Center

Full name of responsible person
Shahnaz Najar

Street address
Ahvaz Eeast 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, Kiyan abad, 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

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

City
Ahvaz

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

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Position
Masters of Midwifery

Other areas of specialty/work

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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