Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparative study on the effects of Hypericum Perforatum and passion flower on the menopausal symptoms of women referring to Isfahan city health care centers

Protocol summary

Summary

Objectives : The aim of this research was to pinpoint and compare the effects of Hypericum Perforatum and Passion Flower on menopausal symptoms. Design : The present study was a three-phase, two group quasi-experimental clinical trial conducted in 1388 in Isfahan City Treating and Hygienic Centers. Setting and conduct :59 menopausal women After giving complete explanations to the qualified women about the stages and the kind of research and taking written consent, the Personal Fertility Features Questionnaire and the Cooperman's index were filled out and individuals were randomly assigned into two groups. Randomization was done by using the random number table, so that the odd numbers were assigned to Hypericum Perforatum Group and the even numbers to Passion Flower Group. Afterwards, throughout the third and sixthweeks of intervention, the Cooperman's index was filled out again. Participants including major eligibility criteria : the women who had not experienced menopause in the last year؛ women who were at first 5-year period of menopause؛ those who had the score of 15 from Cooperman's index for menopausal symptoms. Exclude criteria: Those women who were suffering؛ whatsoever؛ from severe gastrointestinal problems or were not able to take the medications or had side effects following using the two medications of the study were omitted. Intervention :The procedure for taking the medications was like this: Hypericum Perforatum, 160 mg effervescent table, three times a day, PassionFlower, 30 mg, 20% Pass P drop , 20 drops in morning , and 40 drops before sleeping. Afterwards, throughout the third and sixthweeks of intervention, the Cooperman's index was filled out again. Main outcome measures (variables): The Cooperman's index consists of eleven symptoms of menopause (heatstroke, insomnia, fatigue, depression, palpitation, headache, muscular and joint-relatedpains, anger, vertigo.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031712835N1**
Registration date: **2013-05-25, 1392/03/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-05-25, 1392/03/04

Registrant information

Name
Zahra Asali
Name of organization / entity
Toyserkan Azad university
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Science, Ŝchool of Nursing and Midwifery, Maryam Kian pour, Adress: Isfahan University of Medical Science, Vice chancellor for research, Hezar jirib Street, Isfahan

Expected recruitment start date

2009-06-22, 1388/04/01

Expected recruitment end date

2009-10-07, 1388/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effects of Hypericum Perforatum and passion flower on the menopausal symptoms of women referring to Isfahan city health care centers

Public title

effect of st jhon's wort and passion flower on monopausal symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

include criteria :the women who had not experienced menopause in the last year؛ women who were at first 5-year period of menopause؛ those who had the score of 15 from Cooperman's index for menopausal symptoms؛ women who did not have any known psychological disturbances and did not have any record for these problems؛ women who didn't suffer from thyroid diseases؛ psychosomatic disorders؛ pheochromocytoma؛ carcinoid syndrome؛ leukemiacancer and any known systemic diseases such as blood pressure, diabetes, cardiovascular problems؛ those who did not take hormonal treatments؛ nutritional supplements؛ herbal drugs؛ homeopathy for soothing their menopausal symptoms and did not take medications that could have intervention with Hypericum Perforatum and Passion Flower and finally؛ did not have a BMI more than 30 kg/m2 and precocious menopause (before the age of 40 years). exclude criteria : Those women who were suffering whatsoever, from severe gastrointestinal problems ؛ were not able to take the medications or had side effects following using the two medications of the study were omitted.

Age

From **40 years** old to **58 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **59**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan university Medical Science

Street address

Isfahan university medical Science , HezarJirib Street, Isfahan

City

Isfahan

Postal code

Approval date

2009-06-22, 1388/04/01

Ethics committee reference number

388102

Health conditions studied

1

Description of health condition studied

Menopause Symptoms

ICD-10 code

n95

ICD-10 code description

Menopausal and other perimenopausal disorders

Primary outcomes

1

Description

cooperman's Hot flash : not , Mild, Moderate , Sever

Timepoint

pre-intervention, the third week of intervention, and the sixthweek of intervention.

Method of measurement

Questionnaire cooperman's index

2

Description

cooperman's Depression: not , Mild, Moderate , Sever

Timepoint

pre-intervention, the third week of intervention, and the sixthweek of intervention.

Method of measurement

Questionnaire cooperman's index

3

Description

cooperman's Insomnia: not , Mild, Moderate , Sever

Timepoint
pre-intervention, the third week of intervention, and the sixthweek of intervention.
Method of measurement
Questionnaire cooperman's index

4

Description
cooperman's Anxiety: not , Mild, Moderate , Sever
Timepoint
pre-intervention, the third week of intervention, and the sixthweek of intervention.
Method of measurement
Questionnaire cooperman's index

5

Description
cooperman's Headache: not , Mild, Moderate , Sever
Timepoint
pre-intervention, the third week of intervention, and the sixthweek of intervention.
Method of measurement
Questionnaire cooperman's index

6

Description
cooperman's Palpation: not , Mild, Moderate , Sever
Timepoint
pre-intervention, the third week of intervention, and the sixthweek of intervention.
Method of measurement
Questionnaire cooperman's index

Secondary outcomes

1

Description
Vaginal dryness
Timepoint
6weeks after intervention
Method of measurement
Yes, No

Intervention groups

1

Description
Intervention group 1: st john's wort group : tab 160 mg, 3 times a day, for 6 weeks
Category
Treatment - Drugs

2

Description
Intervention group 2 : passion flower drop : 20drops in mornings, 40 drops at night for 6 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan City Treating and Hygienic Centers: Navab safavi
Full name of responsible person
Zahra Asali
Street address
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Recruitment center
Name of recruitment center
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Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research,Isfahan University of Medical Science, School of Nursing and Midwifer

Full name of responsible person
Maryam Kian pour , phon number 00983116680048

Street address
Isfahan university medical Scinece, Hezar jirib Street,Vice chancellor for research Isfahan

City
Isfahan

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,Isfahan University of Medical Science, School of Nursing and Midwifer

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
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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