Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of Agnugol, Cimifugol , Soyagol , vitagnus and EsCitalopram in reducing menopausal symptoms in postmenopausal women

Protocol summary

Study aim

Comparison of the effect of Agnogel, Simifogel and Suyagel, Vitagnos and S-citalopram drug in reducing menopausal symptoms of postmenopausal women.

Design

This study will be conducted in the form of a double-blind randomized clinical trial and the third phase of the trial with parallel groups, on 200 postmenopausal women who are referred to Isfahan Endocrine and Metabolism Research Center and specialist colleagues' office in Isfahan city. People are included in the study by available sampling method. The method of randomization, the random allocation of people to the studied groups will be completely random and will be done by Random Allocation software.

Settings and conduct

This study will be conducted as a double-blind randomized clinical trial on 200 postmenopausal women who refer to the Endocrine and Metabolism Research Center and Specialist Associates Clinic in Isfahan. The participants, the co-investigator of the intervention effects, and the person analyzing the plan will be unaware of the allocation of people to groups and the type of medicine received.

Participants/Inclusion and exclusion criteria

Obtaining a score of 5 and above from the MRS questionnaire, 12 months or more have passed since menopause Use of various hormonal drugs, use of drugs that interfere with the studied drugs. History of some diseases.

Intervention groups

The first group: one cimifugol coated tablet daily The second group: one soyagol coated tablet daily The third group: one Agnugol coated tablet daily 4th group: one Vitagnus coated tablet daily The fifth group: one coated tablet of Escitalopram daily

Main outcome variables

Total score of menopausal symptoms; physical symptoms score; mental symptoms score; Urinary and genital symptoms score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080902001181N4**
Registration date: **2023-01-21, 1401/11/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-21, 1401/11/01**
Update count: **0**

Registration date

2023-01-21, 1401/11/01

Registrant information

Name

Mansour Siavash

Name of organization / entity

Isfahan Endocrine and Metabolism Research Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-07, 1401/10/17

Expected recruitment end date

2023-04-06, 1402/01/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Agnugol, Cimifugol , Soyagol , vitagnus and EsCitalopram in reducing menopausal symptoms in postmenopausal women

Public title

Comparison of the effect of Agnugol, Cimifugol , Soyagol , vitagnus and EsCitalopram

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Obtaining a score of 5 and above from the MRS questionnaire 12 months or more have passed since menopause Age between 45 and 65 years

Exclusion criteria:

Presence or history of breast and uterine cancer, abnormal vaginal bleeding, liver, kidney, thyroid, depression and known anxiety disorders. Use of progestins, contraceptive pills, GNRH agonists and antagonists Taking drugs that interact with the studied drugs, such as warfarin, tamoxifen, antipsychotics, and dopamine antagonists.

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 200 eligible patients will be selected non-randomly and in the order of referral. Allocation of people to the five study groups will be done by "Random Allocation" specialized software and by Simple randomization method. First, on the main page of the software, we enter the number of intervention groups (5 groups) and The name of interventions (based on the code defined for each type of intervention in advance) and the sample size (200 people). Then, by pressing the Generate random list button, a list according to the entered sample size (number 1 to 200) will be presented, which randomly specifies the type of each intervention (designated intervention code) for each person in the order of entering the study. to give Therefore, based on this list and in the order in which people enter the study, the person who distributes the drugs provides the relevant drug to the participants.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, 5 drugs "Agnugol", "Vitagnus", "soyagol", "cimifugol" and "EsCitalopram 10" are prepared and placed in coded packages and provided to the researcher. He also provides the patient without knowing the type of any medicine. Also, the patient, the person recording the clinical and basic information of the patients, as well as the statistical analyst, will not be aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezar jerib Street

City

Isfahan

Province

Isfehan

Postal code

8179964167

Approval date

2022-04-07, 1401/01/18

Ethics committee reference number

IR.ARI.MUI.REC.1401.097

Health conditions studied

1

Description of health condition studied

Menopause

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Total score of menopausal symptoms

Timepoint

The total score of menopausal symptoms is checked at

the beginning of the study (before the start of the intervention), the fourth and the eighth week after the start of the intervention.

Method of measurement

Menopause Rating Scale (MRS)

Secondary outcomes

empty

Intervention groups

1

Description

first intervention group: One CimiFugol coated tablet containing 6.5 mg of dry root of black cohosh plant manufactured by GolDaru Company will be taken daily for 8 weeks every night at a certain time with some water, preferably before going to bed.

Category

Treatment - Drugs

2

Description

second intervention group: One Agnugol coated tablet daily containing 4.8 mg of dry extract of the fruit of Vitex agnus-castus plant (standardized as 0.42-0.58 mg of Ecobin) manufactured by GolDaru Company for 8 weeks every night at a certain time with some water preferably before going to bed.

Category

Treatment - Drugs

3

Description

The third intervention group: once a day before meals, Vitagnus coated tablets containing Vitex agnus-castus plant (standardized as 1.2-3.3 mg of Ecobin) manufactured by Porsina Company will be consumed for 8 weeks.

Category

Treatment - Drugs

4

Description

4th intervention group: They take one Soyagol coated tablet containing 50 mg of soy isoflavone, manufactured by GolDaru Company, for 8 weeks every night at a certain time with some water after meals.

Category

Treatment - Drugs

5

Description

The fifth intervention group: take one 10 mg Escitalopram tablet daily after lunch for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Endocrine Research Center (Sedigheh Tahereh)

Full name of responsible person

Mansour Siavash

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Sedigheh Tahereh Center, Khorram Street, Jomhuri Eslami Square.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
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Mansour Siavash
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Endocrinologist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available