Clinical Trial Protocol
Iranian Registry of Clinical Trials
28 Jun 2019

Compareing effects of Calci Soya Balance and Vitagnuse on menopausal symptoms in Tehran

Protocol summary

Summary
Objectives: this double-blind Controlled Trial study comparing effects of Calci Soya Balance and Vitagnuse on menopausal symptoms (Hot flash, Par aesthesia, Insomnia, Nerves ness, Melancholia, Vertigo, Weakness (fatigue), Arthralgia and myalgia, Headaches, Palpitations, Fornication). Inclusion and exclusion criteria: menopause women with at least one year after amenorrhea history; that suffer of menopausal symptoms. They shouldn't: have history of Brest cancer or have other malignancies, take chemotropic, have active hepatic or renal disease, take HRT or other menopausal treatments, take progesterone or androgen. Study population and sample size: 70 menopause women from Tehran. Intervention: We will explain our study to samples, if they be agree and sign the letter of satisfaction, we will complete demographic and Kupperman menopausal index questioners. Samples will be divided randomly in two groups; one will take Vitagnus and second Calci Soya Balance for 8 weeks. These two drugs will be coded and put in to similar boxes with using order inside them, then one of our coworkers who don't know about coding process will give drugs to samples. At end of every week we will call samples to follow up drug use. Samples can exclude of study every time they want. Kupperman menopausal index questioner will be completed again at the end of 4th and 8th weeks. Two groups will be compared and results will be analyzed by SPSS software. Primary outcomes: treatment of menopausal symptoms

Registrant information
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Recruitment status
Recruitment complete
Funding source
Tehran University of Medical sciences

Expected recruitment start date
2011-09-06, 1390/06/15
Expected recruitment end date
2011-12-06, 1390/09/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing effects of Calci Soya Balance and Vitagnuse on menopausal symptoms in Tehran

Public title
Comparing effects of kinds of drugs on menopausal symptoms

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: menopause women with at least one year after amenorrhea history; that suffer of menopausal symptoms. Exclusion criteria: have history of Brest cancer; take Tamokcifen; take chemotropic; have malignancy; have active hepatic or renal disease; take HRT or other menopausal treatments; take progesterone or androgen.

Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
None
Sample size
Target sample size: 70
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Tehran university of Medical sciences
Street address
Tehran university of Medical sciences, Enghlab square, Tehran
City
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Iran (Islamic Republic of)
Postal code
Approval date
2011-04-17, 1390/01/28
Ethics committee reference number
101/130/90/ص

Health conditions studied

1
Description of health condition studied
menopausal symptoms
ICD-10 code
094-099
ICD-10 code description
Other obstetric conditions, not elsewhere classified

Primary outcomes

1
Description

Secondary outcomes

1
Description
Itch, nausea, diarrhea
Timepoint
End of every week by calling.
Method of measurement
by answering to our questions in phone.

Intervention groups

1
Description
First group will be given Tab Vitagnus oral, 2 times daily for 8 weeks.
Category
Treatment - Drugs

2
Description
Second group will be given Tab Calci Soya Balance oral, 1 time daily for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
Farmanfarmayan Heath Center, Azarbijan st., Tehran
Full name of responsible person
Shahin Bazzazian
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2
Recruitment center
Name of recruitment center
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### Recruitment center

**Name of recruitment center**
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### Recruitment center

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### Sponsors / Funding sources

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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