Comparing 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 pot 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

General information

Acronym
IRCT registration information
IRCT registration number: IRCT201102215878N1
Registration date: 2011-08-11, 1390/05/20
Registration timing: prospective

Registrar information
Name
Shahin Bazzazian
Name of organization / entity
Nursing and Midwifery Faculty of Tehran University of Medical sciences
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+98 21 6692 7171
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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
Tehran

Country
Iran (Islamic Republic of)

Postal code

Approval date
2011-04-17, 1390/01/28

Ethics committee reference number
101/130/90/

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

Timepoint
before intervention- 4 weeks later- 8 weeks later

Method of measurement
Kupperman menopausal index

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 Health Center, Azarbijan st., Tehran

Full name of responsible person
Shahin Bazzazian

Street address
Tehran

City
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Country
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2
Recruitment center
Name of recruitment center
Shahid Ahmady Health Center, Zamzam st., Ghale morghi, Tehran

Full name of responsible person
Shahin Bazzazian

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3
Recruitment center
Name of recruitment center
Akbarabade Health Center, Mahboob mojaz st., Navvab st., Tehran
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4
Recruitment center
Name of recruitment center
Shahid Ayat Health Center, Mahan st., Tehran
Full name of responsible person
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5
Recruitment center
Name of recruitment center
Valiasr Hospital, Imam Khomeini Complex, Keshavarz blvd., Tehran
Full name of responsible person
Shahin Bazzazian
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Sponsors / Funding sources
1
Sponsor
Name of organization / entity
Research deputy of Tehran University of Medical sciences
Full name of responsible person
Research deputy of Tehran University of Medical sciences
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Research deputy of Tehran University of Medical sciences, 6th floor central office, Gods st., Keshavarz blvd., Tehran
City
Tehran
Country
Iran (Islamic Republic of)
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research deputy of Tehran University of Medical sciences
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
Nursing and Midwifery Faculty of Tehran University of Medical sciences
Full name of responsible person
Shahin Bazzazian
Position
MS in Midwifery, Trainer
Other areas of specialty/work
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Person responsible for scientific inquiries
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Full name of responsible person
Shahnaz Golian Tehrane
Position
Person responsible for updating data

Contact

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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