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.
No age limit  
**Gender**  
Female  

**Phase**  
N/A  

**Groups that have been masked**  
No information  

**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  
**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**  
menopausal symptoms  
**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 Heath Center, Azarbijan st., Tehran  
**Full name of responsible person**  
Shahin Bazzazian  
**Street address**  
Tehran  
**City**  
Tehran  

2  
**Recruitment center**  
Name of recruitment center  
Shahid Ahmady Health Center, Zamzam st., Ghale morghi, Tehran  
**Full name of responsible person**  
Shahin Bazzazian  
**Street address**  
Tehran  
**City**  
Tehran
Recruitment center
Name of recruitment center
Akbarabade Health Center, Mahboob mojaz st., Navvab st., Tehran
Full name of responsible person
Shahin Bazzazian
Street address
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City
Tehran

Recruitment center
Name of recruitment center
Shahid Ayat Health Center, Mahan st., Tehran
Full name of responsible person
Shahin Bazzazian
Street address
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City
Tehran

Recruitment center
Name of recruitment center
Valiasr Hospital, Imam Khomeini Complex, Keshavarz blvd., Tehran
Full name of responsible person
Shahin Bazzazian
Street address
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City
Tehran

Sponsors / Funding sources
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
Street address
Research deputy of Tehran University of Medical sciences, 6th flore central office, Gods st., Keshavarz blvd., Tehran
City
Tehran
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
empty
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
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Web page address

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Email
Golian@Tums.ac.ir
Web page address
Person responsible for updating data

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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 |