Clinical Trial Protocol
Iranian Registry of Clinical Trials
09 Mar 2020

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

General information

Acronym

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

Registrant information
Name
Shahin Bazzazian
Name of organization / entity
Nursing and Midwifery Faculty of Tehran University of Medical sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 6692 7171
Email address
shbazzazian@yahoo.com

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
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 Health 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
### 3

**Recruitment center**
- **Name of recruitment center**: Akbarabade Health Center, Mahboob mojaz st., Navvab st., Tehran
- **Full name of responsible person**: Shahin Bazzazian
- **Street address**: Tehran
- **City**: Tehran

### 4

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

### 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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- **City**: Tehran

### 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
- **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**

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### Person responsible for general inquiries

**Contact**
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### Person responsible for scientific inquiries

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Person responsible for updating data

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- **City**: Tehran
- **Postal code**:
- **Phone**:
- **Fax**:

Email
- **Web page address**: empty

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