# EstroG-100 on menopausal women

Submission date Prospectively registered Recruitment status 08/10/2010 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 19/10/2010 Completed [X] Results [ ] Individual participant data Last Edited Condition category 15/08/2012 **Urological and Genital Diseases** 

### Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

### Contact name

Dr Albert Chang

#### Contact details

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## Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

NET-ESTROG-100-001

## Study information

Scientific Title

The effect of herbal extract (EstroG-100) on pre-, peri- and post-menopausal women: a randomised double-blind placebo-controlled study

### **Study objectives**

A standardised mixed herbal extract of Cynanchum wilfordii, Phlomis umbrosa, and Angelica gigas was observed to significantly improve the menopausal symptoms of pre-, peri-, post-menopausal women without weight gain or any serious side effects.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Sterling Institutional Review Board (IRB) (USA) approved on the 21st April 2009 (ref: IRB# 3192; NETESTROG-100-001)

### Study design

Single centre randomised double-blind placebo-controlled study

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Menopausal symptoms

#### **Interventions**

Qualified participants were provided with either EstroG-100 or placebo pill bottles. EstroG-100 (or FGF-271) is a standardised mixed root extract of Cynanchum wilfordii 32.5%, Phlomis umbrosa Turcz 32.5%, and Angelica gigas Nakai 35%.

The EstroG-100 tablet in the clinical study was comprised of 257.05 mg of EstroG-100, corn starch 164.56 mg, microcrystalline cellulose 186 mg, hydroxypropyl methyl cellulose 50 mg, titanium dioxide 15 mg, silicon dioxide 6.2 mg, magnesium stearate 6.2 mg, glycerin mono fatty acid ester 5 mg, and lac color 5 mg.

The placebo tablet consisted of corn starch 359.61 mg, microcrystalline cellulose 248 mg, hydroxypropyl methyl cellulose 50 mg, titanium dioxide 15 mg, silicon dioxide 6.2 mg, magnesium stearate 6.2 mg, glycerin mono fatty acid ester 5 mg, and lac color 5 mg.

Clinical study and placebo materials were separately formulated into 695 mg purple tablets. The pill bottles were packaged in identical bottles so that neither the research team nor the participants were able to differentiate them by appearance. Participants were instructed to take one tablet twice a day orally for 12 weeks.

### Intervention Type

Drug

### **Phase**

Phase IV

### Drug/device/biological/vaccine name(s)

EstroG-100

### Primary outcome measure

- 1. Mean change in scores of self-scored Kupperman Menopause Index (KMI)
- 2. Mean change in scores of each symptom of the questionnaire from KMI
- 3. Mean change in scores of vaginal dryness

The KMI includes hot flash or cold sweat (vasomotor), numbness and tingling (paresthesia), trouble sleeping (insomnia), nervousness, feeling blue or depressed (melancholia), dizzy spells (vertigo), tired feelings (fatigue), rheumatic pain (arthralgia and myalgia), headaches, pounding of the heart (palpitation), and sensation of crawling on the skin (formication).

### Secondary outcome measures

No secondary outcome measures

### Overall study start date

26/05/2009

### Completion date

20/01/2010

## **Eligibility**

### Key inclusion criteria

- 1. Women aged between 42 and 70 years
- 2. Moderate or severe menopausal symptoms (score of greater than or equal to 20) identified by a simplified questionnaire with the Kupperman Menopause Index (KMI)
- 3. Eligibility was re-examined with the results of laboratory, mammogram, and pelvic ultrasound tests

### Participant type(s)

**Patient** 

### Age group

Adult

#### Sex

Female

### Target number of participants

64

### Key exclusion criteria

- 1. Concurrent use of dietary supplement for menopause symptoms
- 2. Any suspicion of breast or endometrial malignancy
- 3. History of using oestrogen or progestin-containing products in past 3 months
- 4. Psychoactive drugs
- 5. Body mass index (BMI) greater than 40 kg/m^2
- 6. Irregular gynaecological bleeding 1 year after menopause
- 7. Hysterectomy
- 8. Uncontrolled hypertension
- 9. Thyroid disease
- 10. Diabetes mellitus
- 11. History of hormone-dependent (gynaecological) cancer
- 12. Drug and alcohol abuse
- 13. Mental disorder
- 14. Abnormality in renal and liver functions
- 15. Personal or family history of breast cancer in first degree relative
- 16. History of clotting disorder such as deep vein thrombosis (DVT)

### Date of first enrolment

26/05/2009

### Date of final enrolment

20/01/2010

## Locations

#### Countries of recruitment

United States of America

Study participating centre 16300 Sand Canyon, Suite 909

Irvine, CA United States of America 92618

# Sponsor information

### Organisation

Naturalendo Tech Co., Ltd (South Korea)

### Sponsor details

414, Daerung Post Tower I 212-8, Guro-dong Guro-gu Seoul Korea, South 152-790 +82 (0)2 2082 3120 jskim@naturalendo.co.kr

### Sponsor type

Industry

### Website

http://www.naturalendo.co.kr

## Funder(s)

### Funder type

Government

### **Funder Name**

Ministry for Food, Agriculture, Forestry and Fisheries (South Korea) - Technology Development Program for Agriculture and Forestry

## **Results and Publications**

## Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2012		Yes	No