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EstroG-100 on menopausal women

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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Sponsor information

Organisation
Naturalendo Tech Co., Ltd (South Korea)

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Sponsor type
Industry

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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