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Assessment of the efficacy of a food supplement in improving menopausal symptomatology.

Submission date
14/03/2016

Recruitment status
No longer recruiting

Registration date
22/04/2016

Overall study status
Completed

Last Edited
03/05/2024

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The menopause happens when a woman stops having periods and is no longer able to get pregnant naturally. Symptoms can include hot flushes, low mood or anxiety, reduced sex drive and problems with memory and concentration. It can also increase the risk of developing osteoporosis, a condition where the bones become weaker and more likely to break. This study investigates whether a food supplement can alleviate the symptoms of the menopause and reduce the likelihood of developing osteoporosis.

Who can participate?
Women aged between 50-55 and going through the menopause.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are given the active food supplement. Those in group 2 are given a placebo (dummy pill). Markers that show whether the participant is at risk of developing osteoporosis are measured for all participats before treatment begins, 6 months after treatment and again after 12 months.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Farcoderm Srl, San Martino Siccomario (Italy)

When is the study starting and how long is it expected to run for?
April 2011 to May 2012

Who is funding the study?
Paladin Pharma S.p.A.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SI.02.DS.L_2011/584+SI.02.DS.L_2011/585

Study information

Scientific Title
Assessment of the efficacy of a food supplement in improving bone turnover markers and menopause-related symptoms in post-menopausal women: a double blind, randomized clinical study of efficacy and safety.

Study objectives
The study is aimed to assess the efficacy of the product in modulating the bone turnover markers and in improving the menopause-related symptoms in post-menopausal women.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Independent Ethical Committee for Non-Pharmacological Clinical trials', 30/03/2011, ref: 2011 /02)

Study design
Monocentric randomized parallel-group interventional study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Menopause and bone turnover

Interventions
Treatment allocation is randomized according to a computer generated restricted randomization list.
The active product was named "Integratore menopausa Lot. FH226" while the placebo product was named "Integratore menopausa Lot. FH314". The active and the placebo products were in tablet form and identical in appearance.

Product efficacy in modulating bone turnover markers was evaluated in 60 subjects (30 subjects per treatment arm) before and after 6 and 12 months treatment. The following markers were measured: deoxypyridinoline (DPD), acid phosphatase (AP), osteocalcin (OC), and bone-specific alkaline phosphatase (BAP). Bone mineral density (BMD) was assessed in a sub-group (n=15) of subjects. Product efficacy on ameliorating menopausal symptomatology was assessed in 60 subjects (30 subjects per treatment arm) before and after 1 and 3 months treatment by means of a validated questionnaire.

Intervention Type
Supplement

Primary outcome measure
1. Urinary Deoxypyridinoline (DPD) measured by means of high-performance liquid cromatography (HPLC), at baseline, and then 6 months and 12 months after treatment
2. Serum Acid phosphatase (AP) measured by means of electrophoresis on agarose gel according to the optimized method by D.G.K.C. at 37°C, at baseline, and then 6 months and 12 months after treatment
3. Serum Osteocalcin (OC) measured by means of electrochemiluminescence technique (ECLIA), at baseline, and then 6 months and 12 months after treatment

4. Serum Bone-specific alkaline phosphatase (BAP) measured by means of colorimetric-enzymatic technique, at baseline, and then 6 months and 12 months after treatment
5. Menopause syndrome by means of Menopause Rating Scale, assessed at baseline, 1 month and 3 months after treatment

Secondary outcome measures
1. Bone mineral density (BMD), measured at baseline, and then 6 months and 12 months after treatment
2. Amelioration of depression associated to menopause
3. Amelioration of sleep

Overall study start date
19/04/2011

Completion date
19/05/2012

Eligibility

Key inclusion criteria
1. Healthy female subjects; Age: between 50 and 55 years old
2. Caucasian ethnicity
3. Body mass index between 20 and 25
4. Slightly overweight (10-20% than ideal weight)
5. Menopause onset (date of last menstrual cycle) not longer than 1 year from the date of study entry
6. Case history characterized by menopausal syndrome psychological complaints (anxiety, emotional instability, depression), hot flush, localized fat and body fat percentage increase
7. No participation in similar trials
8. Absence of disease
9. Agreement not to make any changes to the normal everyday routine
10. Agreement not to use during the study products with activity similar such than the tested product
11. Agreement not to make any changes to eating habits
12. Subjects informed of the trial procedures who have signed an informed consent form

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
50 Years

Upper age limit
55 Years

Sex
Female

Target number of participants
120

Total final enrolment
60

Key exclusion criteria
1. Subjects not satisfying the inclusion criteria
2. Subjects under local or systemic pharmacological treatment
3. Subjects who do not have endometrial hyperplasia in their case history
4. Hormone replacement therapy
5. Metabolic syndrome
6. Depressive syndrome not menopause related
7. Subjects with food intolerances

Date of first enrolment
19/04/2011

Date of final enrolment
19/06/2011

Locations

Countries of recruitment
Italy

Study participating centre
Farcoderm Srl
Via Mons. Angelini. 21
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Sponsor information

Organisation
Paladin Pharma S.p.A.

Sponsor details
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Sponsor type

Industry

Website
http://paladinpharma.it/

ROR
https://ror.org/01x62am17

Funder(s)

Funder type
Industry

Funder Name
Paladin Pharma S.p.A.

Results and Publications

Publication and dissemination plan
Data (all the study data) will be published in an appropriate scientific journal in the field of menopause. The manuscript is under drafting and is planned to be submitted to the identified scientific journal by May 2016.

Intention to publish date
31/05/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/07/2023	03/05/2024	Yes	No