

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

Submission date 14/03/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/04/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/05/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 participants 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?
Dr Nobile Vincenzo
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Quality of life

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(s)

1. Urinary Deoxypyridinoline (DPD) measured by means of high-performance liquid chromatography (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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

50 years

Upper age limit

55 years

Sex

Female

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

San Martino Siccomario

Italy

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Sponsor information

Organisation

Paladin Pharma S.p.A.

ROR

<https://ror.org/01x62am17>

Funder(s)

Funder type

Industry

Funder Name

Paladin Pharma S.p.A.

Results and Publications

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