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Clinical trial to evaluate the effect of a nutritional supplement based on omega 3 fatty acids bleeding and quality of life in women with uterine fibroids

Submission date
18/02/2026

Recruitment status
No longer recruiting

Registration date
18/02/2026

Overall study status
Completed

Last Edited
18/02/2026

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to evaluate the effect of a dietary supplement rich in omega-3 fatty acids, vitamin D, and vitamin B6 on symptoms associated with uterine fibroids (non-cancerous growths of the uterus), as well as fibroid size.

Who can participate?
Women aged from 18 years of age until menopause who have uterine fibroids, abnormal uterine bleeding and/or dysmenorrhoea (period pain)

What does the study involve?
Participants are randomly allocated to one of two groups:
Group 1: "UTERINE FIBROIDS" capsules. One capsule will be taken every 24 hours for 4 months.
Group 2: Placebo capsules. One capsule will be taken every 24 hours for 4 months.

What are the possible benefits and risks of participating?
There may be an improvement in uterine fibroid associated symptoms.

Where is the study run from?
Laboratorios Liconsa S.A., a subsidiary of Insud Pharma (Spain)

When is the study starting and how long is it expected to run for?
July 2024 to May 2025

Who is funding the study?
Laboratorios Liconsa S.A., a subsidiary of Insud Pharma (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific, Public, Principal investigator

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Study information

Scientific Title
Placebo-controlled clinical trial to evaluate the effect of a nutritional supplement containing vitamin D, vitamin B6 and pro-resolving specialised mediators on uterine fibroids

Acronym
EMY-1

Study objectives
To evaluate the effect of a dietary supplement rich in omega-3 fatty acids, vitamin D, and vitamin B6 on symptoms associated with uterine fibroids, as well as fibroid size.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/04/2024, Research Ethics Committee for Medicines at HM Hospitals (Avda. Montepríncipe, 25, Boadilla del Monte, 28660, Spain; +34 (0)91 708 99 00, ext 12588; secretariaceic@mail.hmhospitales.com), ref: Código CEIm HM Hospitales: 24.04.1985E5-GHM

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control

Placebo

Assignment
Parallel

Purpose
Basic science, Health services research, Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Uterine fibroids

Interventions
A randomised, double-blind, parallel, two-arm, placebo-controlled study will be conducted to evaluate the efficacy and safety of a dietary supplement rich in omega-3 fatty acids, vitamin D and vitamin B6 in patients with uterine fibroids by assessing the size and symptoms associated with fibroids, as well as the hypothalamic-pituitary-gonadal axis.
The investigational product and placebo will be manufactured and packaged by Laboratorios Liconsa SL. The label of the investigational food supplement will comply with local laws and regulations. The information on the labels will be in Spanish. During the study, the investigational products must be stored at room temperature, always below 30°C. The following table shows the qualitative and quantitative composition of the nutritional supplement:

Ingredients:
EPA (100–300 mg/g); active/cap: 150 mg EPA
DHA (200–450 mg/g); active/cap: 240 mg DHA
17-HDHA (80–400 mg/kg); active/cap: 180 µg 17-HDHA
18-HEPE (50–400 mg/kg); active/cap: 168 µg 18-HEPE
14-HDHA (40–200 mg/kg); active/cap: 90 µg 14-HDHA
Total: 750,000 mg/cap

Cholecalciferol (Vitamin D3) 1,000,000 IU/g; 2,000 mg/cap; active/cap: 50 µg Vit D (2000 IU)
Pyridoxine hydrochloride (82.26% Vitamin B6); 12.157 mg/cap; active/cap: 10 mg Vit B6

EPA = eicosapentaenoic acid, DHA = docosahexaenoic acid; 17-HDHA = 17-hydroxy-docosahexaenoic acid; 18-HEPE = 18-hydroxy-eicosapentaenoic acid; 14-HDHA = 14-hydroxy-docosahexaenoic acid

Group 1: Nutritional supplement
"UTERINE FIBROIDS" capsules. One capsule will be administered every 24 hours for 4 months.

Group 2: Placebo
Placebo capsules. One capsule will be administered every 24 hours for 4 months.

Intervention Type
Supplement

Primary outcome(s)
1. Abnormal uterine bleeding (AUB) measured using a visual analogue scale (VAS) score with points between 0 and 100 at 16 weeks

2. Dysmenorrhoea measured using a VAS score with points between 0 and 100 at 16 weeks

3. Quality of life measured using the SF-36 Health Questionnaire score and the Female Sexual Function Index (FSFI) score at 16 weeks

Key secondary outcome(s)
1. Percentage change in fibroid volume measured using vaginal scan at baseline and 16 weeks

2. Abnormal uterine bleeding (AUB) measured using VAS score between 0 and 100 points at 8 weeks

3. Dysmenorrhoea measured using VAS score between 0 and 100 points at 8 weeks

4. Quality of life measured using the SF-36 Health Questionnaire score and the Female Sexual Function Index (FSFI) score at 8 weeks

5. Hypothalamic- pituitary-gonadal axis: oestradiol, progesterone, FSH and LH measured using laboratory tests at baseline to 8 weeks (day 56) and 16 weeks (day 112) after treatment

Completion date
01/05/2025

Eligibility

Key inclusion criteria
1. Women over 18 years of age until menopause
2. Uterine myoma ≥2 cm^3 detected and documented by vaginal ultrasound
3. Abnormal uterine bleeding (AUB) as perceived by the patient and/or dysmenorrhoea
4. Signed informed consent

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Total final enrolment
59

Key exclusion criteria

1. Patients with severe acute or chronic diseases (e.g., pancreatitis, hypertriglyceridaemia, liver disease, benign or malignant liver tumour, malignant diseases in the genitals or breasts dependent on sex hormones)
2. Use of drugs that induce microsomal enzymes, especially cytochrome P450, such as phenytoin, phenobarbital, primidone, bosentan, carbamazepine, rifampicin, topiramate, felbamate, griseofulvin, some HIV protease inhibitors (e.g., ritonavir), and non-nucleoside reverse transcriptase inhibitors (e.g., efavirenz), as well as St John's wort preparations
3. Active venous thromboembolic disorder or history of thromboembolic events
4. Past or present arterial and cardiovascular disease (e.g., myocardial infarction, stroke, ischaemic heart disease)
5. Use of anticoagulant medication
6. Known hypersensitivity to vitamin D and/or B6 and/or SPMs
7. Undiagnosed abnormal vaginal bleeding
8. Use of medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir during and 2 weeks prior to study entry
9. Patients using intrauterine devices (IUDs) or intrauterine systems (IUSs)
10. Use of selective progesterone receptor modulators (ulipristal) or GnRH antagonists (ganirelix, centrorelix) or agonists (buserelin, goserelin, leuprorelin, triptorelin) in the last 6 months
11. Pregnancy and breastfeeding throughout the duration of the study
12. Postmenopausal patients
13. Participation in any other clinical trial 30 days prior to study commencement

Date of first enrolment
01/07/2024

Date of final enrolment
02/12/2024

Locations

Countries of recruitment
Spain

Sponsor information

Organisation
Laboratorios Liconsa S.A.

Funder(s)

Funder type

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available