ISRCTN69006251 https://doi.org/10.1186/ISRCTN69006251

# 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?
Prof. Dr. med. Pedro-Antonio Regidor, pedro-antonio.regidor@exeltis.com

# Contact information

### Type(s)
Scientific, Public, Principal investigator

### Contact name
Mr Pedro Antonio Regidor

### Contact details
Adalperostr. 84
Ismaning
Germany
85737
+44 (0)1738938132
pedro-antonio.regidor@exeltis.com

# Additional identifiers

# 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