

An innovative nutraceutical formulation for appetite control and premenstrual syndrome symptom management

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Registration date 25/03/2026	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/03/2026	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Premenstrual syndrome (PMS) is a common condition affecting many women of reproductive age and is characterized by a variety of physical, emotional, and behavioral symptoms occurring before or during the menstrual cycle. Although its pathogenesis is multifactorial and not fully understood, numerous evidence suggest the involvement of hormonal fluctuations, inflammatory responses, oxidative stress, and alterations in the tone of neurotransmitters, particularly serotonin. PMS can significantly impair daily activities, emotional well-being, and social relationships, leading to a marked reduction in quality of life. Common PMS symptoms include joint and muscle pain, headache, bloating, breast tenderness, anxiety, irritability, anger, fatigue, restlessness, and mood swings. In parallel with these symptomatic manifestations, many women report increased hunger and food cravings, which can contribute to weight gain. Despite the availability of pharmacological and non-pharmacological treatments, concerns about side effects and the need for integrated approaches are driving research toward natural and complementary strategies capable of simultaneously addressing multiple aspects of PMS. The aim of this study was to evaluate the effectiveness of a dietary supplement rich in plant extracts (Cinchona bark, Chicory and Gentian roots, Griffonia simplicifolia, and Vitex agnus-castus, named Agrigenina®) specifically selected for their beneficial properties in PMS symptoms.

Who can participate?

Women aged between 18 and 46 years who experience premenstrual syndrome (PMS).

What does the study involve?

Participants are randomly assigned to receive either the nutraceutical supplement Agrigenina® or a placebo. Neither the participants nor the researchers know which treatment is being administered during the study. The study lasts 6 months, including a 2-month run-in period, 3 months of treatment, and 1 month of follow-up. During the treatment period, participants take two capsules per day, approximately 1 hour before meals, during the premenstrual and/or menstrual phase of the cycle. Participants also complete a questionnaire designed to assess hunger perception, premenstrual symptoms, and their impact on daily life.

What are the possible benefits and risks of participating?

The study is designed to evaluate whether supplementation with Agrigenina® can lead to a reduction in hunger perception, together with a decrease in both the emotional symptoms (such as mood changes, irritability, and anxiety) and the physical symptoms commonly associated with premenstrual syndrome. By addressing these aspects simultaneously, the intervention aims to contribute to an overall improvement in participants' well-being and quality of life. The nutraceutical supplement contains plant extracts commonly used in nutraceutical formulations and is expected to be well tolerated. No significant risks are anticipated for participants taking part in this study.

Where is the study run from?

University of Naples Federico II (Italy)

When is the study starting and how long is it expected to run for?

January 2024 to August 2024

Who is funding the study?

NGN Healthcare New Generation Nutraceuticals srl (Italy)

Who is the main contact?

Prof. Bruna Guida, bguida@unina.it

Contact information

Type(s)

Principal investigator

Contact name

Prof Bruna Guida

ORCID ID

<https://orcid.org/0000-0002-1670-7719>

Contact details

Via Sergio Pansini, 5

Naples

Italy

80131

+39 (0)3356296264

bguida@unina.it

Type(s)

Public

Contact name

Dr Fortuna Iannuzzo

ORCID ID

<https://orcid.org/0000-0001-6340-6698>

Contact details

Via Gioacchino Luigi Mellucci 21
Naples
Italy
80147
+39 (0)3385257346
fortuna.iannuzzo@libero.it

Type(s)

Scientific

Contact name

Prof Gian Carlo Tenore

ORCID ID

<https://orcid.org/0000-0002-0251-9936>

Contact details

Via Domenico Montesano, 49
Naples
Italy
80131
+39 (0)81678607
giancarlo.tenore@unina.it

Additional identifiers

Study information

Scientific Title

Randomized, double-blind, placebo-controlled, parallel-group clinical trial evaluating the efficacy of a nutraceutical containing Cinchona bark, Chicory root, Gentian root, Griffonia simplicifolia and Vitex agnus-castus in women with premenstrual syndrome

Acronym

AGRIGENINA

Study objectives

The objective of this study was to evaluate the effectiveness of Agrigenina®, a multicomponent nutraceutical formulation based on plant extracts (Cinchona bark, Gentian root, Chicory root, Griffonia simplicifolia, and Vitex agnus-castus), in the management of symptoms associated with premenstrual syndrome (PMS). Specifically, the study aimed to assess whether supplementation with Agrigenina® during the premenstrual and/or menstrual period could reduce hunger perception and alleviate the severity of emotional, physical, and behavioral PMS symptoms, as well as their impact on quality of life, compared with placebo in a randomized, double-blind, placebo-controlled clinical trial.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 19/06/2023, Scientific Ethics Committee of A.O.U. Federico II – A.O.R.N. Cardarelli (Via Sergio Pansini, 5, Naples, 80131, Italy; +39 (0)817473433; segreteria@comitatoeticofedericoicardarelli.it), ref: Protocol n° 204

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Placebo

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Premenstrual syndrome in women of reproductive age

Interventions

Participants were assigned through 1:1 randomization using a computer-generated randomization list to receive either Agrigenina® or a placebo. Agrigenina® was administered as gastro-resistant capsules containing a multicomponent nutraceutical formulation composed of 200 mg of Cinchona succirubra bark extract, 100 mg of Gentiana lutea root extract, 100 mg of Cichorium intybus root extract, 100 mg of Griffonia simplicifolia extract, and 25 mg of Vitex agnus-castus extract. The supplement was taken as two capsules per day, administered twice daily approximately 1 hour before meals during the premenstrual and/or menstrual phase. The placebo consisted of maltodextrins and was identical in appearance, color, and smell to the active formulation. The study lasted 6 months and included a 2-month run-in period, followed by 3 months of treatment with Agrigenina® or placebo and a 1-month follow-up period after supplementation discontinuation. The Premenstrual Symptoms Screening Tool (PSST) questionnaire was completed at the end of each menstrual cycle throughout the study period, allowing monthly assessment of hunger perception, PMS symptom severity, and their impact on quality of life.

Intervention Type

Supplement

Primary outcome(s)

1. Hunger perception measured using Item 10 of the Premenstrual Symptoms Screening Tool (PSST) questionnaire assessed on a 4-point Likert scale (0 = not at all, 1 = mild, 2 = moderate, 3 = severe) at baseline and at the end of each menstrual cycle during the 2-month run-in period, the 3-month treatment period, and the 1-month follow-up period

Key secondary outcome(s)

1. Premenstrual symptom severity measured using the Premenstrual Symptoms Screening Tool (PSST) (14 items) questionnaire assessed on a 4-point Likert scale (0 = not at all, 1 = mild, 2 = moderate, 3 =severe) at baseline and at the end of each menstrual cycle during the 2-month run-in period, the 3-month treatment period, and the 1-month follow-up period
2. Quality of life measured using the Premenstrual Symptoms Screening Tool (PSST) (5 items) at baseline and at the end of each menstrual cycle during the 2-month run-in period, the 3-month treatment period, and the 1-month follow-up period

Completion date

31/08/2024

Eligibility

Key inclusion criteria

1. Women aged 18–46 years
2. Presence of premenstrual syndrome defined as recurrent somatic, psychological, or behavioral symptoms occurring during the premenstrual and/or menstrual phase in at least four of the previous six menstrual cycles, including the most recent one
3. Regular menstrual cycle
4. Willingness to maintain usual dietary habits and physical activity levels throughout the study period

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

46 years

Sex

Female

Total final enrolment

120

Key exclusion criteria

1. History of chronic diseases such as coagulopathies, diabetes, cardiovascular or renal disorders
2. Cigarette smoking or alcohol consumption
3. Use of nutritional supplements or hormonal medications during the study period
4. Allergy or hypersensitivity to dietary supplements or study product components
5. Irregular menstruation
6. Pregnancy or breastfeeding
7. History of psychological or psychiatric disorders

8. Stressful events occurring in the three months prior to the beginning of the study that could represent a confounding factor

Date of first enrolment

01/01/2024

Date of final enrolment

29/02/2024

Locations

Countries of recruitment

Italy

Sponsor information

Organisation

NGN Healthcare—New Generation Nutraceuticals s.r.l.

Funder(s)

Funder type

Funder Name

Industry

Funder Name

NGN Healthcare—New Generation Nutraceuticals s.r.l.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available