

The effects of nutritional supplementation on premenstrual syndrome (PMS)

Submission date
02/06/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
21/09/2005

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
14/09/2009

Condition category
Urological and Genital Diseases

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

ECN-04-208

Study information

Scientific Title

Acronym

PMS study

Study objectives

Calcium and magnesium in the form of a specific mineral supplement will reduce symptoms of premenstrual syndrome by 20% after 4 months of daily use. This calcium and magnesium supplement used in conjunction with a combination of micronutrients in the form of a specific multi vitamin, mineral and herbal tablet will reduce the symptoms of premenstrual syndrome by 30% after 4 months of daily use.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pre-menstrual syndrome

Interventions

The active group is taking calcium and magnesium, and a multivitamin and mineral supplement and control will take 2 placebo tablets; one will be the same size and shape as the calcium and magnesium supplement, and the second will be the same size and shape as the multivitamin and mineral supplement and contain sufficient riboflavin to maintain blinding.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Calcium, magnesium, multi vitamin, mineral and herbal

Primary outcome(s)

The primary outcome measure for PMS is the Premenstrual Symptom Complex Score, (derived from the Menstrual Health Questionnaire). This is assessed from the means of 23 daily individual symptom ratings and is calculated as shown below.

Luteal Phase Score Follicular Phase Score x 100 Luteal Phase Score

Efficacy is defined as a 20% difference between the premenstrual symptom complex score of those on either of two different dietary supplements compared to those on the placebo.

Subjects will record these details in a daily diary.

Key secondary outcome(s)

No secondary outcome measures

Completion date

30/10/2005

Eligibility

Key inclusion criteria

1. Subject has a regular menstrual cycle of 25 to 35 days
2. Subject is aged over 18 and less than 45 years
3. Subjects general health is normal
4. Subject has had symptoms of PMS in the last year
5. Subject is willing to cease taking other supplements for the period of the trial
6. Subject is willing to comply with the study protocol

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Subject is currently pregnant or lactating
2. Subject who is of childbearing age who is not surgically sterile, who is:
 - a. Not using effective contraception
 - b. Does not agree to have a pregnancy test monthly during the study
3. Subject is currently taking regular medication or dietary supplement(s) and is unwilling to cease
4. Subject self reports that they are experiencing undue stress/relationship problems
5. Subject has any significant disease or disorder
6. Subject is currently undergoing treatment for PMS
7. Subject commenced oral contraceptives in the three months prior to commencement
8. Subject changed oral contraceptives in the three months prior to commencement
9. Subject has had adverse effects from supplements and/or drugs
10. Subjects who are taking steroids
11. Subjects with parathyroid disorders
12. Subjects with thyroid disorders
13. Subjects with affective disorders
14. Subjects who experience photosensitive skin reactions or hypersensitivity to ginger
15. Any disease particularly conditions that interact with gonadotrophins or their releasing factors and those that compromise digestion or absorption of micronutrients

16. Any significant health complaint, problem or disease that in the opinion of the researcher would compromise the study

Date of first enrolment

01/09/2004

Date of final enrolment

30/10/2005

Locations

Countries of recruitment

Australia

Study participating centre

P.O. Box 157

Lismore

Australia

2480

Sponsor information

Organisation

Swisse Vitamins Pty Ltd (Australia)

ROR

<https://ror.org/01gxb6382>

Funder(s)

Funder type

Industry

Funder Name

Swisse Vitamins Pty Ltd (Australia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration