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The effects of nutritional supplementation on premenstrual syndrome (PMS)

Submission date	Recruitment status	[_] Prospectively registered
02/06/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/09/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/09/2009	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Joan O'Connor

Contact details
P.O. Box 157
Lismore
Australia
2480
+61 (0)2 66 20 3649
joconnor@scu.edu.au

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/09/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
120 women in cohort A and 20 women in cohort B

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)

Sponsor details
36-38 Gipps Street
Collingwood

Melbourne
Australia
3066

Sponsor type
Industry

Website
http://www.swisse.com.au

ROR
https://ror.org/01gxb6382

Funder(s)

Funder type
Industry

Funder Name
Swisse Vitamins Pty Ltd (Australia)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration