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The effect of phytoestrogens on symptoms of premenstrual syndrome (PMS) and cognitive performance

Submission date	Recruitment status
12/09/2003	No longer recruiting
Registration date	**Overall study status**
12/09/2003	Completed
Last Edited	**Condition category**
20/06/2008	Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0436118179

Study information

Scientific Title

Study objectives
A randomised double blind, placebo controlled trial of the effects of supplementation of phytoestrogens (PO) (isoflavones - 100 mg/day) on premenstrual symptoms and cognitive performance in 50 women with at least mild premenstrual symptoms for two menstrual cycles per condition is proposed. The main objective is to determine whether PO are more beneficial than placebo supplements in relieving symptoms of PMS and to assess whether the consumption of PO affects cognitive performance in the premenstrual and follicular phases of the menstrual cycle.

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)
Not Specified

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Premenstrual syndrome (PMS)

Interventions
Questionnaire. Randomised controlled trial. Random allocation to:
1. Supplementation with phytoestrogens
2. Placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
phytoestrogens

Primary outcome(s)
1. Mood questionnaires, urine and blood test.
2. Cognitive function tests.

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/12/2007

Eligibility

Key inclusion criteria
50 premenstrual women - university based study of staff, student volunteers and women from surrounding areas within Yorkshire.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/2002

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Psychology Department
Leeds
United Kingdom
LS2 9LN

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results on symptom effects	01/05/2005		Yes	No