

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

Submission date

12/09/2003

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

12/09/2003

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

20/06/2008

Condition category

Urological and Genital Diseases

☐ 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

Study design

Randomised controlled trial

Primary study design

Interventional

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