

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

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/06/2008	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

1. Mood questionnaires, urine and blood test.
2. Cognitive function tests.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2002

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

Age group

Adult

Sex

Female

Target number of participants

50

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

England

United Kingdom

Study participating centre
Psychology Department
Leeds
United Kingdom
LS2 9LN

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.doh.gov.uk>

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

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

Study outputs

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