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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

## 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 |