

# The efficacy of treatment with St Johns Wort for premenstrual syndrome (PMS)

**Submission date**

02/02/2009

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

03/04/2009

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

01/03/2010

**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

**Contact name**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

UI04-6748

## Study information

**Scientific Title**

A randomised, double-blind, placebo-controlled trial to test the efficacy of Hypericum perforatum (St Johns Wort) as a treatment for premenstrual syndrome (PMS)

**Study objectives**

The primary objective of the proposed study is to determine whether hypericum perforatum (900 mg/day) is more beneficial than placebo supplements in relieving premenstrual symptoms in women diagnosed as having at least mild pre-menstrual syndrome (PMS).

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Leeds (West) Research Ethics Committee approval obtained 23 June 2005 (ref: 04/Q1205/173)

**Study design**

Interventional single centre randomised double-blind placebo-controlled cross-over study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Pre-menstrual syndrome (PMS)

**Interventions**

Random allocation to:

1. Hypericum perforatum tablets (900 mg/day)
2. Placebo tablets

After the three screening cycles, all women underwent a placebo run-in phase of two menstrual cycles, after which they were randomised to receive either Hypericum perforatum or placebo for two menstrual cycles. After a placebo-treated washout cycle, women were crossed over to placebo or Hypericum perforatum for a further two menstrual cycles.

**Intervention Type**

Drug

**Phase**

## Phase IV

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

Hypericum perforatum (St John's Wort)

### Primary outcome measure

Improvement in premenstrual symptoms measured using the Daily Symptom Report, completed daily by the participants throughout the trial.

### Secondary outcome measures

1. Other mood questionnaires, completed at the end of each week throughout the trial:
  - 1.1. State Trait Anxiety Inventory
  - 1.2. Beck Depression Inventory
  - 1.3. Aggression Questionnaire
  - 1.4. Barratt Impulsiveness Scale
2. Hormone levels, measured during the follicular (days 5 - 10) and luteal (days -6 to -1) phases of study cycles 3 (screening), 5 (placebo run-in), 7 (treatment phase I: Hypericum perforatum or placebo), 8 (washout) and 10 (treatment phase II: placebo or Hypericum perforatum):
  - 2.1. Follicle stimulating hormone (FSH)
  - 2.2. Luteinising hormone (LH)
  - 2.3. Oestradiol
  - 2.4. Progesterone
  - 2.5. Prolactin
  - 2.6. Testosterone
3. Cytokine concentration, measured during the follicular (days 5 - 10) and luteal (days -6 to -1) phases of study cycles 3 (screening), 5 (placebo run-in), 7 (treatment phase I: Hypericum perforatum or placebo), 8 (washout) and 10 (treatment phase II: placebo or Hypericum perforatum):
  - 3.1. Interleukin-1 beta (IL-1beta)
  - 3.2. Interleukin-6 (IL-6)
  - 3.3. Interleukin-8 (IL-8)
  - 3.4. Interferon-gamma (IFN-gamma)
  - 3.5. Tumour-necrotising factor-alpha (TNF-alpha)

### Overall study start date

01/06/2005

### Completion date

01/01/2007

## Eligibility

### Key inclusion criteria

1. Women aged between 18 and 45 years
2. In good physical and psychological health (assessed by a clinician)
3. Regular menstrual cycles (25 - 35 days)
4. Experiencing at least a 30% increase in the total scale score on the Daily Symptom Report from their follicular (cycle days 5 - 10) to luteal (cycle days -6 to -1) phase in at least two out of three menstrual cycles

### Participant type(s)

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

41

**Key exclusion criteria**

1. Using hormonal contraception or treatment
2. Pregnant or breast-feeding
3. Taking prescribed or over the counter medication for PMS
4. Taking prescribed drugs which could interact with Hypericum perforatum
5. Photosensitive
6. Meeting criteria for anxiety and/or depression

**Date of first enrolment**

01/06/2005

**Date of final enrolment**

01/01/2007

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Institute of Psychological Sciences**

Leeds

United Kingdom

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## **Sponsor information**

**Organisation**

University of Leeds (UK)

**Sponsor details**

Room 10.110  
Level 10, Worsley Building  
Leeds  
England  
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LS2 9JT

**Sponsor type**

University/education

**Website**

<http://www.leeds.ac.uk/>

**ROR**

<https://ror.org/024mrxd33>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

The Rosalind Bolton Bequest (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?
<a href="#">Results article</a>	results	01/03/2010		Yes	No