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

Submission date	Recruitment status	[_] Prospectively registered
02/02/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/04/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/03/2010	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Sarah Canning

Contact details
Institute of Psychological Sciences
University of Leeds
Leeds
United Kingdom
LS2 9JT
s.e.canning@leeds.ac.uk

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
LS2 9JT

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
Room 10.110
Level 10, Worsley Building
Leeds
England
United Kingdom
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?
Results article	results	01/03/2010		Yes	No