

# The effects of a herbal combination on menopausal symptomatology

**Submission date**

26/06/2006

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

17/08/2006

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

06/01/2021

**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**

Prof Marc Cohen

**Contact details**

School of Health Sciences

PO Box 71

Bundoora

Australia

3083

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

9/03

## Study information

Scientific Title

The effects of a herbal combination on menopausal symptomatology

**Study objectives**

Does this herbal combination have a beneficial effect on the vasomotor and/or psychological symptoms associated with menopause?

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

RMIT Human Research Ethics Committee approval obtained 23 June 2003 (reference: Project 9 /03).

**Study design**

Randomised double blind placebo controlled parallel trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet**

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

Menopause

**Interventions**

St John's wort (*Hypericum perforatum*) and Chaste tree/berry (*Vitex agnus castus*) versus an identical placebo treatment.

**Intervention Type**

Drug

**Phase**

Not Specified

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

St John's Wort (*Hypericum perforatum*) and Chaste tree/berry (*Vitex agnus-castus*)

**Primary outcome measure**

Scores on the Greene Climacteric scale and flushing and sweating counts

**Secondary outcome measures**

Scores on the High Definition Imaging (HDI) instrument and Utian Quality of Life Scale

**Overall study start date**

01/09/2003

**Completion date**

01/12/2005

## **Eligibility**

**Key inclusion criteria**

1. All participants must be women aged between 40 and 60 years
2. Amenorrhoeic for 12 months or more or at least three months' amenorrhoea in the past 12 months
3. A minimum of five flushes (including sweating episodes) per 24 hour period
4. A minimum score of 20 on the Greene Climacteric scale
5. Prospective participants are required to obtain a general medical examination from a general practitioner

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

103

**Total final enrolment**

93

**Key exclusion criteria**

1. Women on other concomitant treatment for menopausal symptoms, any formula containing the trial herbs, or any medication known to interact with either herb
2. Women with any major health condition (such as history of epilepsy or seizures)
3. Pre-existing cancer, renal or liver disease, diabetes mellitus requiring treatment, uncontrolled hypertension
4. Bipolar disorder, severe depression, current major psychiatric disorder, history of mania)
5. Substance abuse
6. Medically or surgically induced menopause
7. Spasmodic dysmenorrhoea not associated with Pre-Menstrual Syndrome (PMS)
8. Undiagnosed vaginal bleeding (in post-menopausal women)
9. Known photosensitivity
10. Known intolerance to St Johns Wort (*Hypericum perforatum*) or Chaste tree/berry (*Vitex agnus-castus*)
11. Pregnancy or attempting to conceive
12. Women participating in another clinical trial

**Date of first enrolment**

01/09/2003

**Date of final enrolment**

01/12/2005

## **Locations**

**Countries of recruitment**

Australia

**Study participating centre**

School of Health Sciences

Bundoora

Australia

3083

## **Sponsor information**

**Organisation**

RMIT University (Australia)

**Sponsor details**

School of Health Sciences

GPO Box 2476V

Melbourne, Victoria

Australia

3001

**Sponsor type**

University/education

**Website**

<http://www.rmit.edu.au>

**ROR**

<https://ror.org/04ttjf776>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

Australian College of Phytotherapy

**Funder Name**

Jean Hailes Foundation

**Funder Name**

RMIT university

**Alternative Name(s)**

Royal Melbourne Institute of Technology, RMIT

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Australia

## 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>	post-hoc analysis results	23/06/2009	06/01/2021	Yes	No