

The effects of a herbal combination on menopausal symptomatology

Submission date 26/06/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/08/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/01/2021	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

Protocol serial number
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).

Primary study design

Interventional

Study design

Randomised double blind placebo controlled parallel trial

Study type(s)

Treatment

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(s)

Scores on the Greene Climacteric scale and flushing and sweating counts

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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 University - Melbourne, RMIT Australia, RMIT

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Australia

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