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The effects of a herbal combination on menopausal symptomatology

Submission date	Recruitment status	[_] Prospectively registered
26/06/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/08/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/01/2021	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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