ISRCTN19413357 https://doi.org/10.1186/ISRCTN19413357

A multicentre, randomised, double-blind, placebo-controlled clinical trial to evaluate the use of Chinese herbal medicine in the management of endometriosis: a prospective study

Submission date	Recruitment status	[_] Prospectively registered
04/05/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/06/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/09/2007	Urological and Genital Diseases	[_] Record updated in last year

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
HEC 02/098

Study information

Scientific Title

Acronym
Endoherb

Study objectives
The hypothesis is that the formulated Chinese herbal treatment shows no significant difference than a placebo in the management of the symptoms of endometriosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the University of Western Sydney's Ethics Committee on the 8th August 2002 (ref: HEC 02/098).

Study design
A multicentre, randomised, double-blind, placebo-controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
A specific Chinese herbal formula (Endoherb) versus placebo.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Pain intensity due to endometriosis, measured quantitatively on the VAS and qualitatively as descriptive values.

Key secondary outcome(s))

1. Quality of life using the 36-item Short-Form health survey (SF-36) and a study design health survey tool
2. Serum CA 125 levels

Completion date
15/11/2005

Eligibility

Key inclusion criteria
1. Women, aged 18 - 43 years
2. Diagnosed with endometriosis by laparoscopy and the severity staged (grade I - IV)
3. At least three months of pain measuring more than 30 mm on visual analogue scale (VAS) scale

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Menopause
2. Pregnancy
3. Liver diseases
4. Suffering from diabetes mellitus
5. Suffering from malignancies
6. Hormonal treatments
7. Anti-depressant treatments
8. Immunosuppressive conditions and treatments

Date of first enrolment
15/11/2004

Date of final enrolment
15/11/2005

Locations

Countries of recruitment
Australia

Study participating centre
497 South Road
South Australia
Australia
5035

Sponsor information

Organisation
University of Western Sydney (Australia)

ROR
https://ror.org/03t52dk35

Funder(s)

Funder type
University/education

Funder Name
University of Western Sydney (Australia)

Alternative Name(s)
UWS

Funding Body Type
Private sector 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