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).

### Primary study design
Interventional

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

### 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