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
04/05/2006

Recruitment status
No longer recruiting

Registration date
02/06/2006

Overall study status
Completed

Last Edited
20/09/2007

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
Pain intensity due to endometriosis, measured quantitatively on the VAS and qualitatively as descriptive values.

Secondary outcome measures
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

Overall study start date
15/11/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
100 participants (50 in each arm)

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)

Sponsor details
Centre for Complementary Medicine
Locked Bag 1797
Penrith South DC
New South Wales
Sydney
Australia
1797

Sponsor type
University/education

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

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