ISRCTN31072075 https://doi.org/10.1186/ISRCTN31072075

The effects of Chinese herbal medicine in polycystic ovary syndrome (PCOS)

Submission date
18/01/2013

Recruitment status
No longer recruiting

Registration date
31/01/2013

Overall study status
Completed

Last Edited
06/02/2017

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Polycystic ovary syndrome (PCOS) is a common female hormonal condition that is associated with a range of symptoms such as menstrual irregularities, excessive hair growth and weight gain. Whilst some scientific research has been conducted in China on the use of Chinese herbal medicine (CHM) for PCOS, the effects have not been tested scientifically in the UK. We would like to carry out a pilot study to see whether it is possible to test how well this form of treatment works. This will include seeing if women with PCOS are willing to participate, whether the questionnaires and tests we use are acceptable and whether there are any measurable effects of herbs on symptoms of PCOS. The main aim of this study is to see whether or not it is feasible to offer women with PCOS Chinese herbs for their symptoms for example, are women with PCOS interested in using herbs for their symptoms; if women drop out of the study, what are their reasons for dropping out; are there measurable benefits of herbs in women with PCOS and are there differences between the two herbal treatments offered? The results of this study will help us see whether or not it is worthwhile continuing to investigate the use of Chinese herbs for PCOS in larger studies and if so, how these larger studies should be organised.

Who can participate?
You are able to take part if you are female, are aged 18-44, have been diagnosed with PCOS, have irregular or no periods, and are not currently trying to conceive.

What does the study involve?
Before you join the study, we will need you to answer some questions about your medical history and treatments you are currently receiving to make sure that you are suitable to take part. If you are found to be suitable to take part in the study, we will invite you to attend an initial appointment with a member of the study team to have a simple blood test and to explain what the study will involve. If you are happy with the information that you have been provided and agree to take part, we will then ask you to sign a consent form. As part of the study, you will be prescribed one of two types of Chinese herbs for 6 months. No placebo or dummy treatment will be used. You will have a 50/50 chance of receiving either type of herbs which will be decided randomly by a computer. During the study, neither you nor your herbalist will know which type of Chinese herbs you are taking. Over the 6 months, we will ask you to attend the clinic to see a qualified herbalist. You will also be asked to fill out some questionnaires about your periods and

other symptoms of PCOS and undergo some physical assessments such as measuring your weight, waist and hip circumferences and hair growth.

What are the possible benefits and risks of participating?
By taking part in the study, you will be entitled to Chinese herbs and consultations with experienced herbalists, normally costing £800-1000. You will receive careful monitoring throughout the study by the study team and may experience improvements in some of your symptoms. Your participation in this study will be helpful in supporting research for women with PCOS, even if you do not experience improvements in your own symptoms. Herbs are occasionally associated with side-effects such as diarrhoea, loss of appetite and headaches in the first 48 hours. These usually subside after 48 hours and will be monitored closely by your herbalist. Herbs can sometimes aggravate current symptoms that you have but this is usually a temporary side-effect and will be monitored closely. Chinese herbs have rarely been associated with kidney or liver damage. The dosages in this study have been carefully measured and we will monitor for any effects on your kidney and liver with blood tests. Medical concerns will be escalated to a registered medical doctor on the study team and study procedures will be overseen by the study team consisting of GP researchers and qualified herbalists. You may experience minor discomfort or bruising following the blood test.

Where is the study run from?
This study has been designed and organised by academic staff and a PhD student at the University of Southampton (UK).
Participants will attend visits from two clinics that are involved in this trial which are in Hemel Hempstead (Hertfordshire) and in Primrose Hill (North London) in the UK.

When is the study starting and how long is it expected to run for?
January 2013 to January 2014

Who is funding the study?
Funding has been provided by the National School for Primary Care Research (NSPCR) as part of the National Institute for Health Research (NIHR), and also by the University of Southampton department of Primary Care and Population Sciences (UK).

Who is the main contact?
Lily Lai, Research Training Fellow
lywl1g10@southampton.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof George Lewith

Contact details
Complementary and Integrated Medicine Research Unit
University of Southampton
Aldermoor Health Centre
Aldermoor Close
Southampton

United Kingdom
SO16 5ST

Additional identifiers

Protocol serial number
Protocol Version 4.0, University of Southampton ethics and RGO approval (ref:3977)

Study information

Scientific Title
Polycystic Ovary syndrome: Randomised feasibility pilot study using Chinese Herbal medicine to explore Impact on Dysfunction

Acronym
ORCHID

Study objectives
PCOS is the most common female endocrine disorder affecting women of reproductive age and has an estimated prevalence of 6-18%. It is a heterogeneous condition that is associated with symptoms such as menstrual irregularities, depression, hirsutism and abdominal obesity.

For this present study and in order to provide information for an adequately powered main study, we ask the following primary feasibility question:
1. Is oligomenorrhoea and amenorrhoea appropriate as the primary outcome measure for the main study?
1.1. Is Chinese herbal medicine (CHM) effective for regulating periods in PCOS?
1.2. Can menstrual data be obtained?
1.3. Is regulating menses important to women with PCOS?

Secondary feasibility questions are:
1. Are other measures more appropriate for investigation as the primary outcome measure for the main study?
1.1. What are the treatment effects at 6 months in secondary outcome measures?
1.2. What other symptoms are women with PCOS reporting to be particularly distressing to them?
2. What is the safety profile of Chinese herbal medicine (CHM)?
2.1. Are changes in liver and kidney functions observed following CHM administration?
2.2. What is the frequency, nature and severity of adverse events?
3. How should the CHM intervention in the main study be delivered?
3.1. Are there differences observed between the two CHM groups?
3.2. Is the CHM treatment acceptable to participants?
5. Can a double-blind, randomised trial with CHM for PCOS be conducted?
5.1. What is the eligibility and consent rate?
5.2. What is the retention rate and reasons for loss-to-follow up?
5.3. Are methods used for patient-blinding and practitioner-blinding, randomisation and allocation concealment appropriate?
5.4. Are data collection methods and frequency acceptable to participants?

Ethics approval required

Old ethics approval format

Ethics approval(s)
University of Southampton ethics committee, 22/11/2012, Ref: 3977

Study design
Randomised patient and practitioner-blind feasibility and pilot study with two parallel groups

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Polycystic ovary syndrome

Interventions
Comparison of two CHM interventions, involving a combination of Chinese medicinal herbs in powdered form, routinely prescribed in the UK for symptoms of PCOS and manufactured according to Good Manufacturing Practice (GMP). Participants will be prescribed CHM to be taken twice daily for 6 months.

Participants and practitioners will remain blind to assignment.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
To answer the primary feasibility question:
1. Menstrual frequency and variability of cycle length using menstrual diary data
2. Percentage of missing menstrual diary data
3. Measure Yourself Medical Outcome Profile (MYMOP)

Key secondary outcome(s))
To address the secondary feasibility questions:
1. Treatment effects at 6 months in proposed main-study secondary outcome measures of weight, BMI, waist-hip ratio, hirsutism, Polycystic Ovary Syndrome Questionnaire (PCOSQ), Dermatology Life Quality Index (DLQI), MYMOP
2. Treatment safety: liver and kidney function tests and the frequency, severity and nature of adverse events
3. Treatment adherence: weighing of herbal medicines and self-reported using Morisky Medication Adherence Scale (MMAS)
4. Eligibility and consent rate
5. Retention rate and reasons for loss to follow-up
6. Security of practitioner blinding by Bang Blinding Index

7. Adherence to study protocol by measuring compulsory and non-compulsory study follow-up rates
8. End-of-study feedback questionnaire

Completion date
21/01/2014

Eligibility

Key inclusion criteria
1. Females aged 18-44
2. Present with oligomenorrhoea (irregular periods) defined as intervals between periods of >35 days and <200 days, OR with amenorrhoea (absence of periods), defined as intervals between periods of ≥200 days
3. Diagnosis of PCOS consistent with the Rotterdam criteria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
44 years

Sex
Female

Key exclusion criteria
1. Suffer from other causes of hyperandorgenism and menstrual irregularities e.g. thyroid or prolactin disorders, acromegaly, Cushing's syndrome
2. Are pregnant, or suspected to be pregnant
3. Are breastfeeding within 6 months of study start date
4. Are receiving treatments or medications prohibited for use during the study
5. History of liver or kidney pathologies
6. History of psychotic illness
7. Present with current and major depression
8. Current harmful and hazardous drinking
9. Allergies to herbal ingredients contained in the CHM treatments
10. Do not have the spoken or written language skills to take part owing to study assessments and materials being available only in English
11. Present with abnormal liver and/or kidney function

Date of first enrolment

21/01/2013

Date of final enrolment
21/01/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
University of Southampton (UK)

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - National School for Primary Care Research (NSPCR) (RCS Ref 10-0894)

Funder Name
University of Southampton Primary Care and Population Sciences (UK)

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	results	03/02/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes