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Electroacupuncture added to metformin treatment in patients with polycystic ovary syndrome and overweight

Submission date
13/08/2020

Recruitment status
No longer recruiting

Registration date
18/08/2020

Overall study status
Completed

Last Edited
07/07/2021

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Polycystic Ovary Syndrome (PCOS) is a common condition that affects how a woman's ovaries work, it is present in 10% of women population in reproductive age and is a common hormone disorder.
Acupuncture is a treatment derived from ancient Chinese medicine. Fine needles are inserted at certain sites in the body for therapeutic or preventative purposes.
Acupuncture has been shown to improve ovary function in PCOS patients.
This study aims to investigate the effectiveness of electroacupuncture and drug therapy on PCOS symptoms.

Who can participate?
Adult PCOS patients who are also overweight.

What does the study involve?
The intervention group receives adjuvant electroacupuncture in addition to pharmacological therapy. Participants have to make a visit for acupuncture therapy 3 times per week, with a break of 1 - 2 days between each visit, for a total of 12 visits. Participants also receive metformin drug treatment.
The control group receives the same procedure, with the difference of instead electroacupuncture, the participants have only needles with patches on the skin.
Patients will be interviewed about their condition at the start and end of the study. They will also have an ultrasound examination.

What are the possible benefits and risks?
Participants who are enrolled in the study benefit from receiving relatively safe adjuvant therapy which is believed to be more effective for no additional cost.
The risks and side effects that may arise during the study are local skin infection, mild pain or light bleeding during needle insertion, or electrical shock due to machine malfunction (a very rare occurrence).

Where is the study run from?
Cipto Mangunkusumo Hospital (Indonesia)

When is the study starting and how long is it run for?
March 2018 to August 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
18-03-0254

Study information

Scientific Title
Combination of electroacupuncture and pharmacological treatment in improving menstrual cycle and ovarian morphology in PCOS patients: double-blind randomized clinical trial

Study objectives
1. Electroacupuncture and pharmacological combination therapy is more effective in shortening the menstrual cycle in PCOS patients, compared to conventional pharmacological therapy
2. Electroacupuncture and pharmacological combination therapy is more effective in decreasing ovarian volume in PCOS patients, compared to conventional pharmacological therapy
3. Electroacupuncture and pharmacological combination therapy is more effective in decreasing the number of antral follicles in PCOS patients, compared to conventional pharmacological therapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/03/2018, Health Research Ethics Committee - University of Indonesia and Cipto Mangunkusumo Hospital (HREC-FMUI/CMH, Jl. Salemba 6, Jakarta Pusat, DKI Jakarta, Indonesia; +62 21 315 7008; ec_fkui@yahoo.com), ref: 0243/UN2.F1/ETIK/2018

Primary study design
Interventional

Study design
Single-center interventional double-blinded randomized controlled trial

Study type(s)
Treatment

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

Interventions
Treatment group (EA Group): The patient receives adjuvant electroacupuncture. Sites used are the Zhongji (CV3), Guanyuan (CV4), Qihai (CV6), Tianshu (ST25), Shuidao (ST28), Zusanli (ST36), Chengsan (BL57), and bilateral Sanyinjiao (SP6) with a continuous wave frequency of 2 Hz, the

intensity is set based on the comfort of the patient. Subjects have to make a visit for acupuncture therapy 3 times per week, with a break of 1-2 days between each visit, for a total of 12 times. Pharmacological therapy used is metformin 2 x 500 mg per day.

Control group (SA Group) received the same procedure, instead of electroacupuncture, they have only needles with patches on the skin (sham treatment). Pharmacological therapy used is metformin 2 x 500 mg per day.

Randomization.com is used to allocate the subjects to treatment groups. The subjects and the evaluators are blinded to this allocation.

Follow up: The total duration of follow up for all study arms is 1 month.

Intervention Type
Mixed

Primary outcome(s)
1. Menstrual cycle length is measured in days using interview at baseline (before 1st session) and the end of acupuncture sessions (after 12th session)
2. Ovarian volume is measured in ml using transvaginal ultrasonography at baseline (before 1st session) and the end of acupuncture sessions (after 12th session)
3. Number of antral follicles is measured using transvaginal ultrasonography at baseline (before 1st session) and the end of acupuncture sessions (after 12th session)

Key secondary outcome(s)
Menstruation occurrence is measured using interview at baseline (before 1st session) and the end of acupuncture sessions (after 12th session)

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. 18 - 40 years old
2. BMI > 23kg/m²
3. Volunteering to join this research and giving informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Total final enrolment
44

Key exclusion criteria
1. Suffering from malignancy
2. Suffering from hypertension (blood pressure >140/90 mmHg, JNC 7 criteria)
3. Suffering from diabetes mellitus (fasting blood sugar >126 mg/dL, PERKENI 2015 criteria)
4. Currently in lactation
5. Suffering from endocrine disorders associated with steroid sex hormones such as congenital adrenal hyperplasia, Cushing's syndrome, and androgen-secreting tumor diagnosed by a gynecologist
6. Currently undergoing pharmacological therapy related to dominant follicles stimulation such as clomiphene citrate, letrozole, FSH within 3 months
7. Subjects undergoing acupuncture therapy in the 12 weeks prior to recruitment
8. Subjects with absolute contraindications to electroacupuncture therapy such as: the first trimester of pregnancy, patients in a state of shock or coma, body temperature >38 degrees C, septicemia, tuberculosis of the skin or other local skin infection, heart rhythm disorders and patients with pacemakers, hypertension
9. Subjects with relative contraindications to electroacupuncture therapy such as: a history of epilepsy, pain and acute edema, and in patients with metal implants

Date of first enrolment
02/04/2018

Date of final enrolment
27/07/2018

Locations

Countries of recruitment
Indonesia

Study participating centre
University of Indonesia - Cipto Mangunkusumo Hospital
Jl. Pangeran Diponegoro No.71
Jakarta
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Sponsor information

Organisation

University of Indonesia and Cipto Mangunkusumo Hospital

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository.

IPD sharing plan summary
Stored in repository