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Effect of combined electroacupuncture and medical therapy on insulin resistance in polycystic ovary syndrome patients

Submission date
04/11/2020

Recruitment status
No longer recruiting

Registration date
18/11/2020

Overall study status
Completed

Last Edited
17/11/2020

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 affects 7-10% of women worldwide. It is considered a serious problem as it lasts a lifetime and is not just tied to pregnancy. Electroacupuncture is a form of acupuncture where a small electric current is passed between pairs of acupuncture needles. This study aims to measure the effect of electroacupuncture and drug treatment on insulin resistance in PCOS patients.

Who can participate?
Women aged 18-40 with PCOS and body mass index (BMI) over 23 kg/m²

What does the study involve?
Participants are randomly allocated to be treated with electroacupuncture or sham electroacupuncture three times per week, with intervals of 1-2 days, for 12 times. The drug treatment used is metformin 2 x 500 mg per day. Blood samples are taken to measure insulin and blood glucose at the 1st and 12th session.

What are the possible benefits and risks of participating?
Participants could benefit from an improvement in insulin resistance. The risks include hematoma (collection of blood) at the point the acupuncture needle is inserted.

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

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

Who is funding the study?
investigator initiated and funded

Who is the main contact?
R Muharam
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
0248/UN2.F1/ETIK/2018

Study information

Scientific Title
Combination of electroacupuncture and pharmacological treatment in improving insulin resistance (HOMA-IR) in polycystic ovary syndrome patients: a double-blind randomized clinical trial

Study objectives
The combination of electroacupuncture and pharmacological therapy has better efficacy to improve insulin sensitivity.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 26/03/2018, Ethics Committee of the Faculty of Medicine, University of Indonesia (Jl. Salemba Raya no.6 Jakarta 10430, PO Box 1358; +62 (0)21 3912477; humas@fk.ui.ac.id, office@fk.ui.ac.id), ref: 18-03-0254

Study design
Double-blind randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Interventions
Randomization was done using a computer-based random block table randomizer. The doctors, paramedics, and laboratory personnel do not know whether the subject receives electroacupuncture or sham electroacupuncture. The participants also do not know whether they receive electroacupuncture or sham electroacupuncture.

Participants receive electroacupuncture three times per week, with intervals of 1-2 days, for 12 times. The pharmacological therapy used is metformin 2 x 500 mg per day.

Intervention Type
Other

Primary outcome measure
Median HOMA-IR index measured using initial fasting insulin and initial fasting blood glucose at the 1st and 12th session

Secondary outcome measures
1. Mean fasting blood glucose measured using a blood sample before and after intervention at the 1st and 12th session
2. Median fasting insulin measured using a blood sample before and after intervention at the 1st and 12th session

Overall study start date
26/03/2018

Completion date
20/09/2018

Eligibility

Key inclusion criteria
1. 18-40-year-old females
2. BMI >23 kg/m²
3. Volunteer to join and give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
44

Total final enrolment
44

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
29/03/2018

Date of final enrolment
19/09/2018

Locations

Countries of recruitment
Indonesia

Study participating centre

University of Indonesia – Cipto Mangunkusumo Hospital
Faculty of Medicine
Jl. Pangeran Diponegoro No.71, Kenari, Kec. Senen
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Sponsor information

Organisation
University of Indonesia

Sponsor details
Division of Reproductive Immunoendocrinology
Department of Obstetrics & Gynecology
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Sponsor type
University/education

Website
http://www.ui.ac.id/

ROR
https://ror.org/0116zj450

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
11/11/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from R Muharam (rmuharam@yahoo.com).

IPD sharing plan summary
Available on request