

The role of exercise in treatment of women with Polycystic Ovary Syndrome (PCOS): mechanisms of action

Submission date

22/12/2008

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

23/01/2009

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

28/08/2012

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.jeanhailes.org.au/research/closed-projects/916-pcos-and-insulin-resistance-study>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A prospective cohort study examining the effect of 12 weeks of intensive endurance exercise on insulin sensitivity and muscle insulin signalling in overweight women with or without polycystic ovary syndrome (PCOS)

Acronym

PCOS

Study objectives

Women with polycystic ovary syndrome (PCOS) have both intrinsic insulin resistance and extrinsic obesity-related insulin resistance mediated via different mechanisms. Exercise is an effective intervention decreasing central adiposity reducing extrinsic insulin resistance and improving symptoms.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the Southern Health Human Ethics Committee in March 2005

Study design

Prospective cohort non-randomised un-blinded controlled trial

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Polycystic ovary syndrome

Interventions

Both PCOS and non-PCOS women underwent the same study protocol. From baseline, participants in the two groups undertook a 12 week programme of supervised intensified

endurance exercise (1 hr/day; 3 x per week). Two different exercise sessions alternated, performing 1 hour of moderate intensity treadmill walking to elicit work rates of 70% of maximal oxygen consumption (VO₂max) or 75 - 85% of maximal heart rate (HRmax). These were adjusted as fitness improved. Alternate sessions involve high intensity exercise with intermittent walking up an incline with 6 - 8 repetitions (5 minutes walking, 2 minutes recoveries) targeting 90 - 100% VO₂max or 95 - 100% HRmax. Participants progress to 8 repetitions by the 4th week, with 1 minute of recovery. After 12 weeks of exercise all baseline measurements were repeated.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Effects on insulin resistance, measured at baseline and after 12 weeks of exercise.

Secondary outcome measures

1. Clinical symptom improvement
2. Insulin signalling
3. Mitochondrial function

Measured at baseline and after 12 weeks of exercise.

Overall study start date

01/03/2005

Completion date

01/03/2008

Eligibility

Key inclusion criteria

1. Overweight women (body mass index [BMI] greater than 27 kg/m²)
2. Aged 18 - 40 years with PCOS and without
3. Diagnosed from a history of perimenarchal onset of irregular cycles (less than 21 days or greater than 35 days)
4. Clinical manifestations of hyperandrogenism (hirsutism, acne) or biochemical hyperandrogenism with elevation of at least one circulating ovarian androgen (1990 National Institute of Health [NIH] criteria)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

40 Years

Sex

Female

Target number of participants

30

Key exclusion criteria

1. BMI less than 27 kg/m²
2. Other concurrent medical conditions
3. Ongoing use of the oral contraceptive pill (OCP)
4. Pregnancy or desire for pregnancy
5. Secondary causes of amenorrhoea and hyperandrogenism

Date of first enrolment

01/03/2005

Date of final enrolment

01/03/2008

Locations**Countries of recruitment**

Australia

Study participating centre

SHPM, Monash Institute of Health Services Research

Melbourne

Australia

3168

Sponsor information**Organisation**

Southern Health (Australia)

Sponsor details

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Sponsor type
Government

Website
<http://www.southernhealth.org.au>

Funder(s)

Funder type
University/education

Funder Name
Monash University (Australia) - New Investigator Award 2005

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2012		Yes	No