

Hormonal and metabolic effects of diet and exercise programs in obese women with polycystic ovary syndrome (Hormonella och metabola effekter av diet- och motionsprogram hos överviktiga kvinnor med polycystiskt ovariesyndrom)

Submission date 02/05/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 01/06/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/03/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

N/A

Study information

Scientific Title

Hormonal and metabolic effects of diet and exercise programs in obese women with polycystic ovary syndrome : a prospective randomised controlled trial

Study objectives

Combined treatment with diet and exercise is superior than diet and exercise alone to improve reproductive function in women with polycystic ovary syndrome (PCOS)

Ethics approval required

Old ethics approval format

Ethics approval(s)

CI Research Ethics Committee at Karolinska Hospital North (KI forskningsetikkommitté Nord vid Karolinska sjukhuset), 29/08/2002, No 02-243

Study design

Prospective randomised controlled 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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Polycystic ovary syndrome (PCOS)

Interventions

The interventions lasted for four months, with monthly visits and follow-up was continued for more than one year after termination of the programs.

The diets were designed individually under the close supervision of a dietician. It was recommended that total daily caloric intake be reduced by at least 600 kcal/d in comparison to

before the intervention, while maintaining a well-balanced diet containing 55-60% carbohydrates, 25-30% fat (10% saturated) and 10-15% proteins, according to Swedish nutritional recommendations (SNO) in 2005. A strict schedule of three main meals and two or three snacks was also introduced. Food intake was assessed by self-reporting once every 24 hours during the 4 days both immediately before and at the end of intervention.

The exercise program was supervised by a physiotherapist and was designed to enhance both the type and level of physical activity to a level conforming to each individual patient's capacity, goals and interest at the beginning of this intervention. Physical activity was assessed utilising pedometers (Yamax SW-200 Tokyo, Japan) during the four days immediately before and at the end of the program.

During both types of intervention monthly follow-ups with the dietician and/or physiotherapist were scheduled for discussion of the goals achieved, as well as setting up new goals for the next month.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Immediately before this study, after four months of intervention and at the time of the long-term follow-up, each patient underwent a general health control involving determination of blood pressure, weight, height and waist/hip ratio (WHR).

1. All gynecological examinations including transvaginal ultrasound using Sonoline SI-250 equipment (Siemens Healthcare Diagnostics, Deerfield, IL, USA) were performed by the same investigator. The ovarian parameters evaluated were the maximal number of follicles in one plane and the volumes of the largest follicle and of the entire ovary. Menstrual bleedings were recorded and ovulation confirmed on the basis of an elevation in the serum level of progesterone during the luteal phase of the menstrual cycle.
2. For determination of body composition, the patients were examined by dual energy X-ray absorptiometry (DXA) employing a Lunar Prodigy Advance whole body scanner (GE medical systems, Fairfield, CT, USA).

Secondary outcome measures

Improved insulin sensitivity - In a resting and fasting state at 8:00 am a blood sample was collected from a peripheral vein and the serum separated by centrifugation and stored at 70 degree celsius, pending analysis for hormones, binding proteins and glucose.

Evaluated immediately before this study, after four months of intervention and at the time of the long-term follow-up

Overall study start date

01/01/2003

Completion date

31/12/2009

Eligibility

Key inclusion criteria

Women aged 18-40 years diagnosed with PCOS and having body mass index (BMI) > 27

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

40 Years

Sex

Female

Target number of participants

45

Key exclusion criteria

1. The presence of other disease or a different endocrine disorder
2. An eating disorder
3. Smoking
4. Continuous medication including insulin sensitising drugs

Date of first enrolment

01/01/2003

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Sweden

Study participating centre

Department of Women's and Children's Health

Stockholm

Sweden

SE-171 76

Sponsor information

Organisation

Karolinska Institute (Sweden)

Sponsor details

Department of Women's and Children's Health
c/o Angelica Hirschberg
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Sponsor type

University/education

ROR

<https://ror.org/056d84691>

Funder(s)

Funder type

Research council

Funder Name

The Swedish Research Council (Sweden)

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	01/10/2013		Yes	No