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Metabolic and hormonal effects of weight loss in patients with polycystic ovary syndrome

Submission date
10/10/2012

Recruitment status
No longer recruiting

Registration date
16/11/2012

Overall study status
Completed

Last Edited
28/02/2023

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 one of the most common hormone disorders that affects women of childbearing age. The symptoms of PCOS include enlarged (polycystic) ovaries, high levels of male hormones (hyperandrogenism), irregular periods (anovulation), infertility and miscarriage. Furthermore, women with PCOS have a high risk of developing metabolic disorders such as diabetes and heart disease. Lifestyle changes (weight loss and exercise) are an important part of treatment. However, many patients fail to lose weight by lifestyle changes or quickly regain weight. Structured lifestyle management with long-term support may improve patients' compliance. The main aim of this study is to evaluate an individualized diet and exercise program for weight loss in overweight women with PCOS.

Who can participate?
Overweight/obese women aged 18-40 with PCOS

What does the study involve?
Participants are randomly allocated into two groups. Group A starts with an active treatment of an individualized diet and exercise program, and Group B begins with self-treatment (lifestyle change on their own). After four months, Group A switches to self-treatment and Group B to active treatment. After eight months, there is a follow-up period of four months with self-treatment for all participants. Investigations at the start of the study and after 4 and 12 months include a blood sample for measurement of hormone levels, vital signs, BMI and waist/hip measurements, quality of life assessment, gynecological examination, measurement of body composition, assessment of liver fat by CT scan, and endometrial, muscle and subcutaneous fat samples.

What are the possible benefits and risks of participating?
All patients undergo a general health examination, gynaecological evaluation and investigations of body composition, which are important information for their own health. If they succeed at losing weight this should be beneficial for future health and fertility. The potential risks of participating in this study are expected to be small. Endometrial biopsies (samples of the lining of the womb) are collected under local anaesthetic, which usually provides good pain relief, but occasionally can give short-term pain and some discomfort. Fat and muscle biopsies are taken

according to a standard sampling technique under local anaesthetic. The sampling can cause bruising and soreness, and in extremely rare cases, infection. A small scar may occur after sampling. The total dose of radiation from the scans is relatively low.

Where is the study run from?
Women's Health Research Unit, Karolinska University Hospital, Stockholm, Sweden

When is the study starting and how long is it expected to run for?
January 2012 to May 2016

Who is funding the study?
Swedish Medical Research Council

Who is the main contact?
Prof. Angelica L Hirschberg

Contact information

Type(s)
Scientific

Contact name
Prof Angelica L Hirschberg

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2012-10-10

Study information

Scientific Title
Metabolic and hormonal effects of weight loss in patients with polycystic ovary syndrome - a prospective randomised controlled trial

Study objectives

A structured lifestyle program with long-term support could lead to sustained weight loss and improved reproductive and metabolic health.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee, Stockholm, 29/02/2012, ref: 2012/146-31/3

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

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

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

Interventions
Active treatment - individualized diet and exercise program:
The diet aims to reduce the intake of fast carbohydrates, in favour of foods with low glycemic index (GI), giving a smoother postprandial glucose curve and lower insulin levels. A protein drink (Natural Balance Shake, from Indevex), consisting of a protein mix from natural foods for a total of 65 kcal is taken 30 minutes before breakfast, lunch and dinner to reduce hunger and prevent excess intake of other foods. Food diary, weight and waist/hip measurements are used for evaluation of the diet. The exercise program is based on each individuals condition, interest and experience and may include walking (with or without poles), water aerobics or fitness at Friskis & Svettis. Pedometers, exercise diary and pulse measurement are used for evaluation. Follow-up is performed in groups twice a week under the guidance of a lifestyle coach. Furthermore, individual coaching takes place via telephone and/or e-mail four times per month.

Self treatment - lifestyle change on their own but including the protein drink
Individual follow-up is performed twice per month at the clinic with control of weight and waist /hip measurements.

Intervention Type
Behavioural

Primary outcome measure
Weight change

Added 04/12/2019: measured in kilograms and a percentage at baseline, 4 and 12 months

Secondary outcome measures
Current secondary outcome measures as of 04/12/2019:
1. Menstrual function defined as menstrual cycle type (regular cycle, oligomenorrhoea and amenorrhea) reported by participants at baseline, 4 and 12 months as well as changes to the proportion of study participants in each category at all review points
2. Body composition (total fat percentage, trunk fat mass and lean body mass) assessed by a dual-energy X-ray absorptiometry (DEXA) scanner at baseline, 4 and 12 months as well as changes to the body composition between baseline and the review points
3. Insulin sensitivity assessed by the oral glucose tolerance test, fasting insulin levels and the HOMA-index at baseline, 4 and 12 months and changes to these between baseline and the review points
4. Psychological well being as assessed by the Psychological General Well Being Index (PGWBI) at baseline, 4 and 12 months and changes to the PGWBI between baseline and the review points
5. Sleep pattern, measured by total sleep time, bedtime and wake up time and sleep efficiency. This is recorded using an Actigraph for 7 consecutive days at baseline and 4 months.
6. Metabolic status as measured by blood lipids, as well as metabolomic analysis of proteins specific for satiety and hunger. This will be done at baseline, 4 and 12 months
7. Liver fat as determined by MRI in a subset of patients at baseline and after 4 and 12 months

Previous secondary outcome measures:
1. Menstrual function
2. Body composition
3. Insulin sensitivity in the endometrium, muscle and fat tissue

Overall study start date
01/01/2012

Completion date
28/05/2016

Eligibility

Key inclusion criteria
1. All criteria for the diagnosis of PCOS should be met (anovulation, hyperandrogenism, polycystic ovaries)
2. 18-40 years
3. BMI between 27 and 38
4. No medication or hormone-containing contraceptives
5. If any kind of hormonal contraception, acceptance for three months of wash-out period before entering the study
6. Accepting a non-hormonal method of contraception such as condoms, IUD during the study or be sterilized
7. Willing to give informed consent in writing

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
40 women with complete investigations

Key exclusion criteria
1. Smoking
2. Use of hormone-containing contraceptives
3. Chronic Illness
4. Ongoing medication

Date of first enrolment
01/01/2012

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institutet
Stockholm
Sweden
SE 171 76

Sponsor information

Organisation
Karolinska Institutet (Sweden)

Sponsor details
c/o Angelica Lindén Hirschberg
Department of Women's and Children's health
Stockholm
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Sponsor type
Research organisation

Website
http://ki.se/

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Research council

Funder Name
Vetenskapsrådet ref: 20324

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Angelica Lindén Hirschberg (angelica.linden-hirschberg@sll.se).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2019	04/12/2019	Yes	No
Other publications	Secondary analysis	10/02/2023	28/02/2023	Yes	No