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A trial to compare the effect of weight loss diets on obese women with polycystic ovarian syndrome (PCOS)

Submission date
15/03/2017

Recruitment status
No longer recruiting

Registration date
24/04/2017

Overall study status
Completed

Last Edited
10/05/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Polycystic ovarian syndrome (PCOS) is the most common hormone disorder in women of reproductive age. Many of these women are overweight or obese and so often also experience insulin resistance (a disorder where the body's cells don't react to insulin as they should do). Up to 50% of women with PCOS develop impaired glucose tolerance (a type of pre-diabetes) or type 2 diabetes by the age of 40. Women with PCOS also have a greater risk of cardiovascular complications, such as heart attack or stroke, and are more likely to develop endometrial cancer (cancer in the lining of the womb). In addition, the symptoms and side effects associated with PCOS have been shown to lead to a reduction in quality of life. Mental health problems such as anxiety, depression and eating disorders are common. Diet has been shown to play a key role in the treatment and management of PCOS. The aim of this study is to explore the effects of a standard weight loss diet given by dietitians and another more aggressive diet which limits intake to 800 calories.

Who can participate?
Overweight or obese women with PCOS who want to lose weight and are aged 18-45 years.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in a very low calorie diet (VLCD), which consists of consuming shakes or soups up to four times a day for eight weeks. Following the eight week diet, participants are supported for a further eight weeks by a dietician to wean them back onto a healthy eating pattern, and reducing down by one shake every two weeks. Those in the second group have their energy requirements calculated by a dietitian and are advised about how to reduce their calorie intake to lose weight. These participants are reviewed every two weeks for eight weeks and supported for a further eight weeks to ensure they keep up the weight loss. Every two weeks throughout the study, participants in both groups are followed up to see if they have lost weight, and blood samples are taken to see how well they are controlling their blood sugar levels and to see what effect their diets have had on their PCOS.

What are the possible benefits and risks of participating?
Participants are likely to benefit from losing weight as a result of taking part in this study. There is a small risk of pain or bruising when blood samples are taken. In addition, there is a risk of experiencing side effects from the VLCD, such as tiredness, hunger, headaches, constipation, hair thinning, bad breath and changes to mood.

Where is the study run from?
Centre for Diabetes, Endocrinology and Metabolism Research, Hull Royal infirmary (UK)

When is the study starting and how long is it expected to run for?
July 2016 to May 2018

Who is funding the study?
University of Hull (UK)

Who is the main contact?
Professor Thozhukat Sathyapalan
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
REC 16/YH/0518

Study information

Scientific Title
A randomised controlled trial to investigate the effect of very low calorie diet (VLCD) vs. an energy deficit approach weight loss diet, over 8 weeks, in obese women with polycystic ovarian syndrome (PCOS)

Study objectives
A very low calorie diet (VLCD) for 8 weeks in obese women with polycystic ovarian syndrome (PCOS) will result in improvements in free androgen index.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Sheffield Research Ethics Committee, 17/02/2017, ref: 16/YH/0518

Study design
Randomised control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
PCOS and obesity

Interventions
Participants are randomised to one of two study arms using the website randomisation.com.

Arm 1 – Very low calorie diet (VLCD): Shakes or soups will be consumed up to 4 times per day providing 800kcal/d. No other food can be consumed only fluids, tea/coffee. The patients will follow this diet for 8 weeks. They will then be supported for a further 8 weeks by the dietitian, gradually weaning them back on to a normal healthy eating pattern and reducing down, by one shake, every 2 weeks.

Arm 2 – Energy deficit diet: The patient will have their energy requirements calculated by a dietitian and advice provided on how to reduce their kcal intake by 600kcal/d to induce weight loss. They will be reviewed every 2 weeks for 8 weeks. They will then be supported for a further 8 weeks by the dietitian to ensure weight loss is maintained. They will be reviewed every 2 weeks.

Intervention Type
Supplement

Primary outcome measure
Free androgen index is measured using a blood test at baseline and 8 weeks later at visit 6.

Secondary outcome measures
1. Total body weight (kg) is measured using Marsden MS-4202L electronic scales at each patient visit, throughout the trial
2. Body composition is assessed using a DEXA scan, at baseline and 8 weeks later at visit 6
3. Waist hip ratio is measured using abdominal circumference tape measure. The tape measure, lying flat will be wrapped around the participant's waist at the midway point between the bottom of the ribs and the top of the hips (iliac crest). These measurements will be then be used to calculate the waist to hip ratio at baseline and 8 weeks later at visit 6.
4. hsC Reactive Protein (CRP) levels are measured is measured using a blood test at baseline and 8 weeks later at visit 6
5. Serum androgens (androstenedione, 17 hydroxy progesterone, DHEAS) are is measured using a blood test at baseline and 8 weeks later at visit 6
6. Fasting lipids profile is measured using is measured using a blood test at baseline and 8 weeks later at visit 6
7. Vascular function is assessed using the EndoPAT 2000 test at baseline and 8 weeks later at visit 6
8. Micro particles are measured using a blood test at baseline and 8 weeks later at visit 6
9. Glucose and insulin levels are measured using OGTT – consuming a glucose load when fasted followed by a blood test. The test will be performed at baseline and 8 weeks later at visit 6. Hba1c and HOMA - IR will be measured via a blood test at baseline and 8 weeks later at visit 6.
10. Compliance to total diet replacement shakes will be measured by the dietitian and the number or unused sachets returned by the patient at visit 4 and 6

Overall study start date
18/07/2016

Completion date
01/05/2018

Eligibility

Key inclusion criteria
1. Women, aged 18-45 years (inclusive)
2. Individuals wishing to lose weight
3. Body Mass Index (BMI)≥30 kg/m2 and <45 kg/m2
4. Have a reliable form of contraception in place
5. Confirmed diagnosis of PCOS based on Rotterdam criteria
6. Willing to commit to 18 weeks of no alcohol and significant alterations to their social life e.g. eating out, holidays, and celebrations

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
20

Key exclusion criteria
1. Non-classical 21-hydroxylase deficiency, hyperprolactinaemia, Cushing's disease and androgen-secreting tumours will be excluded by appropriate tests
2. Any concurrent illness including type 2 diabetes
3. Subjects who are on any of the following medications within 3 months of recruitment
4. Metformin or other insulin-sensitizing medications (e.g., pioglitazone). If cessation of the drug is agreed between the medics and the patient, in preparation for the trial an 8 week washout is required.
5. Hormonal contraceptives (e.g., birth control pills, hormone-releasing implants, etc.). Subjects will be advised to use barrier contraception during the study period. If cessation of the drug is agreed between the medics and the patient, in preparation for the trial a 4 week washout is required.
6. Anti-androgens (e.g., spironolactone, flutamide, finasteride, etc.). If cessation of the drug is agreed between the medics and the patient, in preparation for the trial a 8 week washout is required.
7. Clomiphene citrate or estrogen modulators such as letrozole
8. GnRH modulators such as leuprolide
9. Minoxidil
10. Women planning to conceive.
11. Weight loss of >5 kg within the last 6 months
12. A history of gallstones/gout (diet may raise urate levels)
13. Substance abuse
14. Known cancer
15. Soya intolerance
16. Current treatment with anti-obesity drugs
17. Diagnosed eating disorder or purging in the last 12 months, based on patient reporting or results of EDI-3 RF questionnaire interpreted by clinical psychologist.
18. Pregnant/ considering pregnancy
19. Participants who have required hospitalisation for depression or are on antipsychotic drugs
20. Peri- or post-menopausal women
21. Lactating women
22. Lactose intolerance
23. Acute illness
24. Prescribed oral steroids or other medication that may affect appetite
25. Hospitalised subjects within 3 months of admission to the study
26. Participation in any other clinical interventional studies in the last 3 months

Date of first enrolment
01/05/2017

Date of final enrolment
01/11/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Diabetes, Endocrinology and Metabolism Research
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Sponsor information

Organisation
Hull and East Yorkshire Hospitals

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
University/education

Funder Name
University of Hull

Alternative Name(s)
HU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of the findings of the trial in a high-impact peer reviewed journal.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Thozhukat Sathyapalan (Thozhukat.Sathyapalan@hyms.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2	25/01/2017	24/04/2017	No	Yes
Abstract results		08/11/2021	18/02/2022	No	No
HRA research summary			26/07/2023	No	No
Results article		06/09/2023	10/05/2024	Yes	No