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Low glycaemic index diet and endometrial cancer risk in polycystic ovary syndrome

Submission date	Recruitment status
18/08/2008	No longer recruiting
Registration date	**Overall study status**
13/10/2008	Completed
Last Edited	**Condition category**
01/10/2018	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
1

Study information

Scientific Title
Low glycaemic index diet and endometrial cancer risk in polycystic ovary syndrome

Study objectives
To evaluate the feasibility of a definitive trial to test whether in obese anovulatory women with polycystic ovary syndrome (PCOS) a low glycaemic index (GI) diet compared with a 600 kcal deficit hypo-caloric healthy eating approach results in a greater reduction in such risk factors for endometrial cancer as oestrogen levels, insulin resistance, anovulation, obesity, androgens, endometrial thickness, and prevalence of endometrial hyperplasia and pro-oncogenic expression of molecular markers for such endometrial cancer as Pten, p27, Kras and Cyclin D1.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Derbyshire Research Ethics Committee. Date of approval: 20/06/2006 (ref: 06/Q2401/76)

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Not Specified

Participant information sheet

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

Interventions
1. Baseline clinical interview, assessing menstrual history, current gynaecological, medical and surgical history, past medical, surgical and gynaecological history, family and social history
2. Baseline measurement of body mass index, waist circumference, hip circumference, Ferriman galway score and blood pressure
3. Baseline venepunctures for oestradiol, insulin, glucose, insulin resistance, testosterone, sex hormone binding globulin (SHBG) and luteinising hormone (LH) levels
4. Baseline food diary
5. Baseline pelvic ultrasound scan for endometrial thickness
6. Baseline endometrial biopsy for endometrial hyperplasia and Pten, p27, Kras and Cyclin D1 expression

7. Randomisation to low glycaemic diet or a 600 kcal deficit hypocaloric healthy eating approach
8. Monthly diet classes for the participants, to be taught by a trained dietician for 6 months
9. Monthly assessment of compliance using a food diary
10. Month 6: Repeat assessment of frequency of menstrual cycles, body mass index, waist circumference, insulin, glucose, insulin resistance, testosterone, SHBG, oestradiol, endometrial thickness on pelvic ultrasound, and endometrial biopsy for endometrial hyperplasia and expression of Pten, p27, Kras and Cyclin D1

Women will be flagged at the office of national statistics for the future development of endometrial cancer.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
As this is a pilot study, we do not have a specific biological primary outcome measure. We will however be looking at measures and standard deviations of possible primary outcomes (see below) to inform the definitive trial. The focus of this pilot will be the assessment of the feasibility of the study (eligibility, recruitment, compliance and drop out rate) to help us determine whether an investment in a definitive trial would be value for money.

Possible primary outcomes in the definitive trial include:
1. Change in oestradiol levels, assessed at baseline and Month 6
2. Change in SHBG levels, assessed at baseline and Month 6
3. Change in insulin resistance, assessed at baseline and Month 6
4. Change in expression of Pten, p27, Kras and Cyclin D1 on endometrial biopsy, assessed at baseline and Month 6
5. Prevalence of endometrial hyperplasia on endometrial biopsy at baseline compared with Month 6
6. Proportion of women who have resumed normal menstrual cyclicity by Month 6
7. Reduction in endometrial thickness, assessed at baseline and Month 6
8. Reduction in body mass index by Month 6
9. Change in testosterone levels, assessed at baseline and Month 6
10. In the definitive trial we propose to flag women up at the Office for National Statistics for development of endometrial cancer, however, data collection will be commenced in this pilot study. We do however recognise that even the definitive study may not be powered to detect any significant differences.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/07/2006

Completion date
30/06/2008

Eligibility

Key inclusion criteria
1. An objective diagnosis of polycystic ovary syndrome using the Rotterdam criteria
2. Oligo or amenorrhoea
3. Age above 35
4. Body mass index above 30
5. Patient consent
6. Ability to attend dietary classes at monthly intervals
7. Able to be assessed by pelvic ultrasound imaging and endometrial biopsy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
40

Key exclusion criteria
1. Previous or current history of any cancer
2. Inability to attend diet classes at monthly intervals
3. Regular menstrual periods
4. Age below 35
5. Body mass index below 30
6. Unable to be assessed by pelvic ultrasound imaging and endometrial biopsy

Date of first enrolment
01/07/2006

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
D Floor
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Cancer Research UK (UK)

Sponsor details
Lincoln's Inn Fields
London
United Kingdom
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Sponsor type
Charity

Website
http://www.cancerresearchuk.org

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK) (ref: C20654/A7380)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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?
Protocol article	protocol	01/09/2009		Yes	No
Results article	results	08/03/2011		Yes	No