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BAMBINI: Bariatric surgery vs Medical care for obesity and polycystic ovarian syndrome related infertility

Submission date
22/01/2020

Recruitment status
No longer recruiting

Registration date
11/02/2020

Overall study status
Completed

Last Edited
04/06/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Polycystic ovary syndrome (PCOS) is a common condition that affects how a woman's ovaries work. It is characterised by elevated circulating levels of androgens, problems with ovulation and polycystic ovaries. Difficulty with child bearing is a major cause of emotional distress. Approximately 50% of women with PCOS are overweight or obese and this further impacts on fertility. Weight loss through any means is an effective treatment for improving subfertility in this group of women. Lifestyle modification including healthy eating and increased physical activity is effective in causing short term weight loss but is difficult to maintain long term. Medications also have a positive but modest impact on weight loss. Modern key hole (laparoscopic) surgery is one of the safest operations in the field of surgery and obesity surgery causes significant weight loss. Currently obesity surgery is considered an experimental therapy in women with PCOS for the purpose of having a healthy baby. This study aims to change clinical practice by being the first randomised control trial to compare standard medical care to obesity surgery in women with PCOS, obesity and oligo (irregular) or amenorrhea (absent periods).

Who can participate?
Pre-menopausal women 18 years and older with a BMI ≥ 35 kg/m² with obesity related complications and a diagnosis of PCOS. Participants will need to be within travelling distance of either Imperial College Healthcare NHS trust hospitals (London) or University Hospitals Coventry & Warwickshire NHS Trust (Coventry). This is important due to the need for weekly blood tests and monthly clinical reviews (added 11/03/2020).

What does the study involve?
Participants will be randomly allocated to receive either obesity surgery or standard medical care following review by a trained psychologist (part of standard medical care). Following the intervention, follow-up will be for 12 months and involve weekly progesterone blood tests and monthly clinical review. Trial participants are asked to use non-hormonal contraception for the duration of the trial. Following completion of the trial, women in the standard care group will be given the option for referral for obesity surgery.

What are the possible benefits and risks of participating?
Possible benefits: significant weight loss leading to more regular periods. Also regular contact with a specialist.
Risk: obesity surgery sleeve gastrectomy - common risks bleeding, infection, vitamin deficiencies. Will be explained further in detail by the surgical team. Less common risks include a "leak" (leaking of food from the connections made during surgery), a blood clot in the legs or lung, and weight regain. Very rare risks include malnutrition and death.
The lifestyle modification programme is safe and risk-free.

Where is the study run from?
1. Imperial College Healthcare NHS Trust (UK)
2. University Hospitals Coventry and Warwickshire NHS Trust (UK)

When is the study starting and how long is it expected to run for?
February 2020 to April 2023

Who is funding the study?
1. JP Moulton Charitable Foundation, UK
2. National Institute for Health Research (NIHR) (UK)

Who is the main contact?
1. Dr Suhaniya Samarasinghe (public)
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2. Dr Alexander Miras
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
269196

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1.0, IRAS 269196, CPMS 43641

Study information

Scientific Title
Bariatric surgery vs Medical care for obesity and polycystic ovarian syndrome related infertility

Acronym
BAMBINI

Study objectives
Obesity surgery will be superior to standard medical care in increasing the number of ovulatory cycles in women with PCOS, obesity and oligo or amenorrhoea.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/12/2019, London - Dulwich Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH; +44 (0)207 104 8052; NRESCommittee.London-Dulwich@nhs.net), ref: 19/LO/1540

Study design
Multicentre open-label randomized 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 ovarian syndrome, obesity

Interventions
Patients will be randomised at a ratio of 1:1, stratified by BMI and trial site (using an online randomisation tool).

Intervention - obesity surgery
Control - standard medical care

Participants will be assessed during a screening visit to check that they meet the inclusion criteria for the trial. They will be provided with further written information at this stage. Successful participants will be randomly allocated to either obesity surgery or standard medical care following review by a trained psychologist (part of standard medical care). Following the intervention, follow-up will be for 12 months and involve weekly progesterone blood tests and monthly clinical review. Trial participants are asked to use non-hormonal contraception for the duration of the trial.

Following the completion of the trial, women in the standard care group will be given the option for referral for obesity surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measure as of 20/02/2023:
Number of ovulatory cycles within the 12 months follow-up period - defined as a rise in serum progesterone ≥16 nmol/L, measured using weekly blood progesterone levels

Previous primary outcome measure:
Number of ovulatory cycles within the 12 months follow-up period - defined as a rise in serum progesterone >20 nmol/L, measured using menstrual diaries and weekly blood progesterone levels

Secondary outcome measures

Current secondary outcome measures as of 20/02/2023:
Measured at baseline and then monthly for 12 months (except oral glucose tolerance test):
1. Reproductive profile, liver function tests, lipid profile, HbA1C using blood test
2. Severity of anxiety and depression symptoms measured using the hospital anxiety and depression score (HADS)
3. Multidimensional health profile: health functioning questionnaire score, social functioning questionnaire score, PCOS health-related quality of life score, modified Ferriman-Galwey hirsuitism score, Ludwig visual score, Savin Alopecia Scale score, Cardiff Acne Disability Index
4. Arterial blood pressure (mmHg)
5. Oral glucose tolerance test (at baseline, 6 months and 12 months)
6. Body weight (kg)
7. Waist circumference (cm)
8. Body composition
9. Number of medications measured using patient records
10. Adverse events measured using patient records
11. Pregnancy rates measured using patient records

Previous secondary outcome measures:
Measured at baseline and then monthly for 12 months (except oral glucose tolerance test):
1. Reproductive profile, liver function tests, lipid profile, HbA1C using blood test
2. Mental health measured using the Hospital anxiety and depression scale
3. Multidimensional health profile: health functioning questionnaire score, social functioning questionnaire score, PCOS health-related quality of life score, modified Ferriman-Galwey hirsuitism score, Ludwig visual score, Savin Alopecia Scale score, Cardiff Acne Disability Index
4. Arterial blood pressure (mmHg)
5. Oral glucose tolerance test (only baseline and 6 months)
6. Body weight (kg)
7. Waist circumference (cm)
8. Body composition
9. Number of medications measured using patient records
10. Adverse events measured using patient records
11. Pregnancy rates measured using patient records

Overall study start date
01/11/2019

Completion date
17/04/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/02/2023:
1. Pre-menopausal women 18 years and older
2. BMI more than or equal to 35 kg/m² with obesity-related complications
3. Diagnosis of PCOS based on international evidence-based guidelines for the assessment and management of PCOS 2018

Previous inclusion criteria:
1. Pre-menopausal women 18 years and older
2. BMI more than or equal to 35 kg/m²

3. Obesity-related complications
4. Diagnosis of PCOS based on international evidence-based guidelines for the assessment and management of PCOS 2018
5. Polycystic ovaries on ultrasound

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
80

Total final enrolment
80

Key exclusion criteria
1. Type 1 or 2 diabetes mellitus
2. Specific contraindications to obesity surgery
3. Previous obesity surgery
4. Inability to maintain adequate contraception
5. Use of medications affecting reproductive function at screening/3 months prior
6. Other causes of anovulation
7. Current pregnancy/breastfeeding
8. Any medical/psychological/other condition which would potentially either interfere with the study or cause harm to the volunteer
9. Without access at home to a telephone or other factor likely to interfere with the ability to participate reliably in the study

Date of first enrolment
20/02/2020

Date of final enrolment
01/02/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College Healthcare NHS Trust
Hammersmith Hospital
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Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
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Sponsor information

Organisation
Imperial College London

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Sponsor type
University/education

Website
http://www3.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Charity

Funder Name
JP Moulton Charitable Foundation

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
All publications and presentations relating to the study will be authorised by the Trial Management Group. The first publication of the trial results will be in the name of the Trial Management Group, if this does not conflict with the journal's policy. If there are named authors, these will include at least the trial's Chief Investigator, Statistician and Trial Coordinator. Members of the TMG and the Data Monitoring Committee will be listed and contributors will be cited by name if published in a journal where this does not conflict with the journal's policy. Authorship of parallel studies initiated outside of the Trial Management Group will be according to the individuals involved in the project. The results are likely to be published within the 12 months following the study in peer-reviewed journals and websites, and presented in medical conferences. Participant confidentiality will be ensured at all times and they will not be identified in any publication as these will be anonymised. A lay summary of the key results from the study will be written and sent and/or presented to them.

Intention to publish date
30/11/2023

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 4.0	05/10/2021	29/09/2022	No	No
Statistical Analysis Plan		23/11/2022	05/04/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		20/05/2024	04/06/2024	Yes	No