

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

Submission date 22/01/2020	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 11/02/2020	Overall study status Completed	☒ Statistical analysis plan ☒ Results
Last Edited 04/06/2024	Condition category Nutritional, Metabolic, Endocrine	☐ 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

Integrated Research Application System (IRAS)
269196

Central Portfolio Management System (CPMS)
43641

Protocol serial number
1.0

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

Primary study design
Interventional

Study design
Multicentre open-label randomized controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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 hirsutism 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 hirsutism 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

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**

United Kingdom

England

Study participating centre

Imperial College Healthcare NHS Trust

Hammersmith Hospital

Du Cane Road

London

United Kingdom

W12 0HS

Study participating centre

University Hospitals Coventry and Warwickshire NHS Trust

Clifford Bridge Rd

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Sponsor information

Organisation

Imperial College London

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

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?
Results article	version 4.0	20/05/2024	04/06/2024	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file		05/10/2021	29/09/2022	No	No
Statistical Analysis Plan		23/11/2022	05/04/2023	No	No