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Long-term effects of bariatric surgery in women with Polycystic Ovary Syndrome (PCOS), obesity and irregular or absent menstrual periods

Submission date
05/07/2025

Recruitment status
Recruiting

Registration date
20/10/2025

Overall study status
Ongoing

Last Edited
20/10/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Infertility affects around 1 in 6 couples worldwide. In about 30% of cases, the cause is related to the female partner. One common cause is Polycystic Ovary Syndrome (PCOS), which can lead to irregular or absent periods and problems with ovulation. Obesity can make these symptoms worse. A previous study called the BAMBINI trial showed that weight loss surgery (bariatric surgery) helped women with PCOS and obesity have more regular ovulatory cycles compared to standard medical care. This new follow-up study will look at the long-term effects of that surgery on fertility, metabolism, and quality of life.

Who can participate?
Women who took part in the original BAMBINI clinical trial (https://www.isrctn.com /ISRCTN16668711) may be invited to join this follow-up study.

What does the study involve?
This is an observational study, which means there are no treatments or interventions. Participants will be asked to attend follow-up visits where researchers will collect information about their health, fertility, and well-being over time.

What are the possible benefits and risks of participating?
The main benefit is helping researchers understand how bariatric surgery affects the body in the long term, especially in women with PCOS. There are no significant risks, as this is not a treatment study and no new procedures will be done.

Where is the study run from?
NIHR Imperial Clinical Research Facility at Hammersmith Hospital in London (UK)

When is the study starting and how long is it expected to run for?
April 2025 to September 2026

Who is funding the study?
NIHR Imperial Biomedical Research Centre (UK)

Who is the main contact?
Dr Suhaniya Samarasinghe, suhaniya.samarasinghe@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Bariatric surgery vs. Medical care for obesity and polycystic ovarian syndrome related infertility: Long-term follow-up of the BAMBINI randomised-controlled clinical trial

Acronym
BAMBINI 2.0

Study objectives
To investigate the long-term safety and efficacy of obesity surgery in women with PCOS, obesity and oligomenorrhoea or amenorrhoea

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted, London-Dulwich REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8109; dulwich.rec@hra.nhs.uk)

Study design
Single centre observational study

Primary study design
Observational

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Long-term effects of bariatric surgery in women with Polycystic Ovary Syndrome, obesity and oligomenorrhoea or amenorrhoea.

Interventions
This study will invite all participants who took part in the BAMBINI clinical trial (ISRCTN16668711) and received their randomly allocated intervention to attend for a single visit. At this visit, they will have undergo a detailed medical questionnaire, anthropometric measurements, blood tests for reproductive and metabolic hormones, urine pregnancy test, optional adipose tissue biopsy and genetic blood test.

Intervention Type
Other

Primary outcome(s)
Number of patient-reported menstrual cycles in the last 12 months

Key secondary outcome(s))
Metabolic outcomes:
1. Body weight is measured using calibrated digital scales at baseline and 1 year
2. Body mass index (BMI) is calculated from measured height and weight at baseline and 1 year
3. Waist circumference is measured using a non-stretchable tape at baseline and 1 year
4. Body composition is measured using dual-energy X-ray absorptiometry (DEXA) at baseline and 1 year
5. Plasma lipid concentration is measured using enzymatic colorimetric assays from a fasting blood sample at baseline and 1 year
6. Plasma liver function tests (ALT, AST, ALP, GGT, bilirubin) are measured using automated clinical chemistry analyzers from a fasting blood sample at baseline and 1 year
7. Plasma HbA1c is measured using high-performance liquid chromatography (HPLC) from a fasting blood sample at baseline and 1 year
8. Plasma fasting glucose is measured using a glucose oxidase method from a fasting blood

sample at baseline and 1 year
9. Serum fasting insulin is measured using immunoassay from a fasting blood sample at baseline and 1 year
10. Fasting plasma C-peptide is measured using immunoassay from a fasting blood sample at baseline and 1 year
11. Arterial blood pressure is measured using an automated sphygmomanometer following standard protocols at baseline and 1 year
12. High sensitivity CRP is measured using immunoturbidimetric assay from a fasting blood sample at baseline and 1 year
13. Serum steroid metabolomics is measured using liquid chromatography–mass spectrometry (LC-MS) from a fasting blood sample at baseline and 1 year

Reproductive and hormonal outcomes:
14. Pregnancy, miscarriage, and live birth rates are recorded using a structured reproductive history questionnaire at baseline and 1 year
15. Neonatal outcomes are recorded using a structured birth outcome questionnaire at delivery
16. Use of Assisted Reproductive Technology (ART) is recorded using a structured fertility treatment questionnaire at baseline and 1 year
17. Serum LH is measured using immunoassay from a fasting blood sample at baseline and 1 year
18. Serum FSH is measured using immunoassay from a fasting blood sample at baseline and 1 year
19. Serum oestradiol is measured using immunoassay from a fasting blood sample at baseline and 1 year
20. Serum progesterone is measured using immunoassay from a fasting blood sample at baseline and 1 year
21. Serum SHBG is measured using immunoassay from a fasting blood sample at baseline and 1 year
22. Serum testosterone is measured using immunoassay from a fasting blood sample at baseline and 1 year
23. Serum free androgen index is calculated from total testosterone and SHBG at baseline and 1 year
24. Serum androgen profile including androstenedione and DHEAS is measured using immunoassay from a fasting blood sample at baseline and 1 year
25. Serum AMH is measured using immunoassay from a fasting blood sample at baseline and 1 year
26. Salivary progesterone is measured using enzyme immunoassay from a saliva sample at baseline and 1 year
27. Salivary androgens are measured using enzyme immunoassay from a saliva sample at baseline and 1 year
28. A serum/plasma sample is collected and stored for future measurement of novel markers of reproductive or metabolic function (e.g. INSL3) at baseline and 1 year

Quality of life:
29. Hospital Anxiety and Depression Scale score is measured using the HADS questionnaire at baseline and 1 year
30. Social functioning is measured using the SF-36 questionnaire at baseline and 1 year
31. PCOS-specific quality of life is measured using the PCOSQ questionnaire at baseline and 1 year
32. Hirsutism is measured using the Ferriman-Gallwey score at baseline and 1 year
33. Female pattern hair loss is measured using the Ludwig visual score at baseline and 1 year
34. Female pattern hair loss is measured using the Savin Alopecia Scale score at baseline and 1 year

35. Acne-related quality of life is measured using the Cardiff Acne Disability Index at baseline and 1 year

Other outcomes:
36. Number of medications is recorded using a structured medication inventory at baseline and 1 year

Sub-studies:
37. Adipose tissue biology is assessed using subcutaneous adipose tissue biopsy and histological /molecular analysis at baseline and 1 year
38. Genetic analysis is performed using DNA extracted from peripheral blood samples collected at baseline

Completion date
01/09/2026

Eligibility

Key inclusion criteria
Participants from the BAMBINI clinical trial who received their randomly allocated trial intervention. As part of the initial trial, participants gave their consent to be contacted for potential participation in other research studies.

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Patients who did not receive their randomly allocated intervention as part of the original BAMBINI clinical trial.

Date of first enrolment
01/09/2025

Date of final enrolment
02/05/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR Imperial Clinical Research Facility
Hammersmith Hospital
Du Cane Rd
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Sponsor information

Organisation
NIHR Imperial Biomedical Research Centre

ROR
https://ror.org/01kmhx639

Funder(s)

Funder type
Government

Funder Name
NIHR Imperial Biomedical Research Centre

Alternative Name(s)
NIHR Imperial BRC, Imperial Biomedical Research Centre, BRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

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

Published as a supplement to the results publication