

IRAS ID: 247521

Centre Number: 01

Study Number: 19SM4996

Participant Identification Number for this trial:

CONSENT FORM

Title of Project:**Left gastric artery embolisation (LGAE) for weight loss in patients with BMI 35-50****kg/m²: *EMBI* Trial**Name of Researcher:

Please initial
each box

1. I confirm that I have read the information sheet dated 04-May2022 (version 4.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by representatives of the Sponsor (Imperial College London), by people working on behalf of the Sponsor (Imperial Clinical Trials Unit), by representatives of regulatory authorities or the NHS Trust where it is relevant to taking part in this research. I give permission for these individuals to have access to my records.
4. I give permission for my blood samples and x-ray images to be sent to laboratories in the United Kingdom or abroad for analysis as long as all personal information is removed.
5. I agree to my General Practitioner being informed of my participation in the study including any necessary exchange of information about me between my GP and the research team.
6. I understand that the information held and maintained by St. Mary's Hospital (*Imperial College Healthcare NHS Trust*) may be used to help contact me or provide information about my health

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One copy for participant, 1 for site file, 1 for patient notes

status.

7. I confirm that I understand my medical data will have my name and other directly identifying information removed before it is provided to the manufacturer (*Boston Scientific*) for safety reporting. The manufacturer may also be granted access to the non-identifiable study results for internal research and development and/or commercial purposes.
8. I am happy for the research team to contact me once the study has stopped to find out about my decision on future weight loss treatments.
9. The indemnity arrangements have been discussed with me.
10. In the event that I have private medical insurance, I agree to inform my provider of the study.
11. I agree to take part in the above study.

The following are optional aspects of the trial, please initial the appropriate box:

11. I agree that my blood samples and x-ray images collected during the study will be stored for future research purposes and this material can only be used with ethical committee approval. All testing of my samples, will be coded such that I cannot be identified by the data.

Yes No

12. I am happy to be contacted for possible participation in future research studies in the event that I am not eligible for this study.

Yes No

Name of Participant

Date

Signature

Name of Person obtaining consent

Role of Person obtaining consent

Date

Signature

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