Multimodal Augmented Reality for Operative Guidance in Oncoplastic Breast Surgery

Submission date 07/11/2024	Recruitment status Recruiting	Prospectively registered
07/11/2024	Reciditing	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
11/11/2024	Deferred	☐ Results
Last Edited	Condition category	Individual participant data
11/11/2024	Other	[X] Record updated in last year

Plain English summary of protocol

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Contact information

Type(s)

Principal Investigator

Contact name

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Type(s)

Public, Scientific

Contact name

Dr Philip Pratt

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

306799

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 306799

Study information

Scientific Title

Multimodal Augmented Reality for Operative Guidance in Oncoplastic Breast Surgery

Acronym

MAROG - OBS

Study objectives

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Ethics approval required

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Ethics approval(s)

Approved 10/02/2022, London - Queen Square Research Ethics Committee (RA NRES Centre Manchester, Barlow House, 3rd floor, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8225; queensquare.rec@hra.nhs.uk), ref: 21/PR/1795

Study design

Multi-centre interventional non-control trial in patients undergoing oncoplastic breast procedures

Primary study design

Interventional

Secondary study design

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

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Interventions

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Intervention Type

Other

Primary outcome measure

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Secondary outcome measures

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Overall study start date

10/02/2022

Completion date

31/12/2025

Eligibility

Key inclusion criteria

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Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

100

Key exclusion criteria

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Date of first enrolment

31/05/2022

Date of final enrolment

31/12/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Charing Cross Hospital

Department of Breast Surgery 1st Floor, Charing Cross Hospital Fulham Palace Road London United Kingdom W6 8RF

Study participating centre St George's University Hospital

Department of Plastic and Reconstructive Surgery Blackshaw Road Tooting

Sponsor information

Organisation

Imperial College London

Sponsor details

Research Governance and Integrity Team
Imperial College London and Imperial College Healthcare NHS Trust
Room 215, Level 2
Medical School Building
Norfolk Place
London
England
United Kingdom
W2 1PG

rgit@imperial.ac.uk

Sponsor type

Industry

Website

https://www.medicalisight.com/

ROR

https://ror.org/041kmwe10

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

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Intention to publish date 01/04/2026

Individual participant data (IPD) sharing planNot expected to be made available.

IPD sharing plan summaryNot expected to be made available