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The iBRA (implant breast reconstruction evaluation) study

Submission date 20/01/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/02/2016	**Overall study status** Completed	
Last Edited 16/11/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The iBRA (implant Breast Reconstruction evAluation) Study - a prospective multicentre cohort study to inform the feasibility, design and conduct of a pragmatic randomised clinical trial comparing new techniques of implant breast reconstuction

Acronym
The iBRA (implant Breast Reconstruction evAluation) Study

Study objectives
Implant-based breast reconstruction (IBBR) is the most commonly-performed reconstructive procedure in the UK. The introduction of techniques to augment the subpectoral pocket has revolutionalised the procedure, but there is a lack of high-quality outcome data to support the safety or efficacy of these techniques. Randomised clinical trials (RCTs) are the best way of comparing treatments but surgical RCTs are challenging. The iBRA (implant Breast Reconstruction evAluation) study aims to inform the feasibility, design and conduct of a pragmatic-RCT to examine the effectiveness of new approaches to IBBR.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Phases 1 & 2 do not require ethical approval because they involve the routine collection of clinical and patient reported outcome data as recommended by the 'Oncoplastic Surgery. Guidelines for Good Practice'. This has been agreed with the host organisations. Ethical approval will be obtained for Phase 3, the randomisation acceptability survey as this does constitute research. The University of Bristol will act as the sponsor and proportional ethics review will be obtained prior to commencing this phase of the study.

Study design
Multi-centre prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

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
Implant-based breast reconstruction following mastectomy for breast cancer or risk reduction

Interventions

Phase 1 – A national practice questionnaire (NPQ)

The aim of phase 1 is to understand the current practice of implant-based breast reconstruction in the UK to inform the design of a definitive RCT. Specific objectives of phase 1 are:
1. To establish the number of centres and surgeons able and willing to participate in a future trial.
2. To determine the incidence of each type of IBBR being performed at centre and surgeon level (informing trial design and sample size)
3. To examine how surgeons select suitable patients for surgery (informing the inclusion criteria)
4. To determine how the implant procedures are performed at centre level, especially how lower-pole coverage is achieved (informing trial design)
5. To establish current practice of pre and post-surgical care in IBBR which will inform the use and standardisation of concomitant interventions in the trial
6. To engage surgeons to develop an appreciation of the need for RCTs in IBBR

Phase 2 – A prospective cohort study of patients undergoing implant-based breast reconstruction

The aim of Phase 2 is to understand the practice and outcomes of IBBR in the UK to inform the design of a definitive RCT. Specific objectives of phase 2 are:
1. To determine how implant procedures are carried out at centre level, especially how lower-pole coverage is achieved (informing trial design)
2. To evaluate the practicality of obtaining clinical and patient-reported outcome data and the feasibility of trainees recruiting patients and collecting longitudinal data, with a view to using this approach in a future trial
3. To determine the outcomes of different approaches to IBBR. Including identifying risk factors for adverse outcomes such as the impact of the learning curve (informing entry criteria, primary and secondary outcomes and parameters required for a power calculation).
4. To explore the ability of the BREAST-Q to discriminate between procedure-subtypes and hence its value for use in a future trial
5. To engage and educate consultants and trainees to establish an appreciation of the need for, and a desire to participate in, a future trial in IBBR

Centres identified as performing immediate IBBR from the NPQ (Phase 1) will be eligible to progress to Phase 2, the prospective cohort study. The named supervising consultant will act as the principal investigator for each unit and trainee leads will be responsible for recruitment and data collection.

The study will be piloted in two centres (Liverpool and Bristol) prior to national roll-out to evaluate feasibility and effectiveness of trainee involvement in recruitment and data collection. Methods of data management will also be assessed.

Potential participants will be identified prospectively by the local study team via clinics, local MDTs, consultant surgeons and clinical nurse specialists. Simple demographic, procedure and process data will be collected for each participant. Data will be recorded in an anonymised format using a unique alphanumeric study identification number on a secure web-based database. In-hospital complication data will be collected prospectively by trainee leads. Patients will be reviewed in clinic at 30 days to collect complication and oncology data. Note-review will be performed in patients who do not attend for 30 day follow-up.

Trainees or a locally-designated member of team will approach patients in clinic or during their admission to obtain consent for PROMs assessment. Individual centres will be free to determine

the optimal approach for recruiting patients to this part of the study. PROMs assessment will be by post or e-mail, dependent on patient preference, at 3 and 18-months (for those eligible for long-term assessment) following surgery and will evaluate satisfaction with care, complications and health-related quality of life (BREAST-Q). If consent is obtained, contact details will be sent securely to the co-ordinating centre and questionnaires distributed centrally to optimise compliance, allow accurate follow-up and reduce the incidence of missing data.

Phase 3– An IBBR-RCT acceptability-survey to explore patients' and surgeons' views of proposed trial designs.

The aim of Phase 3 is to investigate the acceptability to patients and surgeons of candidate trial designs generated from phases 1 and 2 to determine a suitable design to progress to a definitive, pragmatic trial. Specific objectives of phase 3 are:
1. To determine the proportion of patients and surgeons willing and able to participate in each candidate study design
2. To determine patients' and surgeons' views regarding the most appropriate primary outcome for the definitive trial
3. To determine the degree of pragmatism (e.g. product selection; technique; variation in pre /peri/post-operative care) that would be acceptable and feasible to surgeons in the definitive trial
4. To explore barriers and facilitators to potential participation in an RCT in IBBR and how these challenges may be overcome

Using phase 1 and 2 data, two RCT acceptability surveys (RCTAS) (one each for patients and surgeons) will be developed by members of the steering group. Respondents will communicate their willingness to participate in different candidate trials; give opinions regarding primary outcomes and surgeons will offer views about the degree of pragmatism that would be acceptable in a future trial.

A qualitative research component will be integrated into Phase 3 of the study to provide an in-depth exploration of the acceptability of proposed trial designs and expand on findings from the questionnaire survey. Respondents to the questionnaire who are willing to be contacted will be purposively sampled and interviewed to explore common and unusual questionnaire responses to enable a more detailed understanding of the acceptability of proposed study designs. Patients and surgeons will be interviewed (with the final number depending on data saturation) using a flexible topic guide to investigate their views on willingness to participate in the proposed study designs, appropriate outcome measures and, for surgeons, the degree of pragmatism that would be acceptable and feasible in the definitive trial

Phase 4 - Design of the definitive RCT

The feasibility, design and conduct of a definitive RCT will be determined by the outcomes of phases 1-3

Intervention Type
Procedure/Surgery

Primary outcome measure
The feasibility study will determine the most appropriate study design. The primary outcome will be identified and outcome data used to inform a sample size calculation. Information from rates of surgery and patient selection criteria will be combined with estimates of surgeon and centre willingness to participate in a trial to assess the feasibility of undertaking a definitive trial that

would achieve target recruitment within 3 years.
The following specific progression criteria will be reviewed at 30 months:
1. At least 40% of surgeons and patients responding to the RCT-Acceptability Survey can agree to participate in an RCT in implant-based breast reconstruction surgery
2. The cohort study data and findings of the RCT-Acceptability Surveys (for patients and surgeons) and qualitative work provide sufficient information to inform the selection of an acceptable and appropriate primary outcome measure to inform the sample size required for main study.
3. Based on the sample size calculation for the chosen primary outcome, the number of centres willing to participate, the anticipated patient consent rate, and data from the incident numbers of patients that are likely to be eligible to participate in a RCT, including information about reconstructive techniques used and to be compared in the trial, the study will be practical and achievable with three years of recruitment. Data from an analysis of NIHR portfolio data (Kaur, MRC North West Hub for Trials Methodology Research, personal communication) shows that the trials recruiting to time and target did so with a median recruitment period of 13 months, interquartile range 8 to 24. 42/45 (93%) recruited successfully within three years. Although these data are for paediatric trials, there is no obvious reason why the results would not be generalisable to recruitment in adult studies.
4. Data from the surveys show that a sufficient number of centres, each with a minimum of 2 participating surgeons are willing and able to participate in the main trial.
5. Feasibility of using the trainee collaborative model to recruit patients and follow them up with <10% missing data over all the specified time points.

Secondary outcome measures
Optimal design and conduct of the RCT

Overall study start date
25/11/2013

Completion date
30/05/2018

Eligibility

Key inclusion criteria
1. Female patients
2. Undergoing immediate IBBR for malignancy or risk-reduction under the care of the breast or plastic surgeons

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants

This feasibility study aims to estimate parameters required for an RCT sample size calculation although the primary outcome most suitable is not yet known. Parameters include estimating the standard deviations for each candidate outcome listed below from which, as a result of this study, the most important outcome will be determined and used as the primary outcome when progressing to an RCT.

Total final enrolment
2108

Key exclusion criteria
1. Women undergoing delayed breast reconstruction
2. Revisional surgery
3. Patients not willing or able to provide informed consent for the patient reported outcomes part of the study

Date of first enrolment
04/02/2014

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
England

Northern Ireland

United Kingdom

Wales

Study participating centre
Royal Liverpool University Hospital
United Kingdom
L7 8XP

Study participating centre
Nottingham Breast Institute
United Kingdom
NG5 1PB

Study participating centre

New Cross Hospital Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Royal Marsden Hospital
United Kingdom
SW3 6JJ

Study participating centre
University Hospitals South Manchester
United Kingdom
M23 9LT

Study participating centre
Brighton and Sussex University Hospitals NHS Trust
United Kingdom
BN1 6AG

Study participating centre
East Lancashire NHS Trust
United Kingdom
BB10 2PQ .

Study participating centre
Arrowe Park Hospital - Wirral University Teaching Hospital NHS Trust
United Kingdom
CH49 5PE

Study participating centre
Barts Health NHS Trust
United Kingdom
E1 2AD

Study participating centre

Leeds Teaching Hospitals NHS Trust
United Kingdom
LS9 7LN

Study participating centre
Belfast Health and Social Care Trust
United Kingdom
BT9 7AB

Study participating centre
Worcester Acute NHS Trust
United Kingdom
WR5 1DD

Study participating centre
The Newcastle on Tyne Hospitals NHS Foundation Trust
United Kingdom
NE1 4LP

Study participating centre
Frimley Health NHS Foundation Trust
United Kingdom
GU16 7UJ

Study participating centre
Bolton NHS Foundation Trust
United Kingdom
BL4 0JR

Study participating centre
Royal Devon and Exeter NHS Foundation Trust
United Kingdom
EX2 7JU

Study participating centre

University Hospitals Coventry and Warwickshire
United Kingdom
CV2 2DX

Study participating centre
West Hertfordshire Hospitals NHS Trust
United Kingdom
HP2 4AD

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
United Kingdom
S10 2JF

Study participating centre
University Hospitals of Leicester NHS Trust
United Kingdom
LE3 9QP

Study participating centre
Airedale NHS Foundation Trust
United Kingdom
BD20 6TD

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
United Kingdom
B15 2WB

Study participating centre
Blackpool Teaching Hospitals NHS Foundation Trust
United Kingdom
FY3 8NR

Study participating centre

Homerton University Hospitals NHS Foundation Trust
United Kingdom
E9 6SR

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
United Kingdom
BD9 6RJ

Study participating centre
Luton and Dunstable University Hospital
United Kingdom
LU4 0DZ

Study participating centre
Dorset County Hospital NHS Foundation Trust
United Kingdom
DT1 2JY

Study participating centre
North Bristol NHS Trust
United Kingdom
BS10 5NB

Study participating centre
Milton Keynes University Hospital NHS Foundation Trust
United Kingdom
MK6 5LD

Study participating centre
Musgrove Park Hospital
United Kingdom
TA1 5DA

Study participating centre

Royal Berkshire NHS Foundation Trust
United Kingdom
RG1 5AN

Study participating centre
Royal Surrey County NHS Foundation Trust
United Kingdom
GU2 7XX

Study participating centre
Northern Lincolnshire and Goole NHS Foundation Trust
United Kingdom
DN15 7BH

Study participating centre
York Teaching Hospital NHS Foundation Trust
United Kingdom
YO31 8HE

Study participating centre
Peterborough and Stamford Hospitals NHS Foundation Trust
United Kingdom
PE3 9GZ

Study participating centre
Royal United Hospital NHS Foundation Trust
United Kingdom
BA1 3NG

Study participating centre
Aneurin Bevan University Health Board
United Kingdom
NP7 7EG

Study participating centre

Countess of Chester NHS Foundation Trust
United Kingdom
CH2 1UL

Study participating centre
University Hospitals North Stafford
United Kingdom
ST4 6QG

Study participating centre
Great Western Hospitals NHS Foundation Trust
United Kingdom
SN3 6BB

Study participating centre
St Helens and Knowsley Teaching Hospitals NHS Trust
United Kingdom
L35 5DR

Study participating centre
Portsmouth Hospitals NHS Trust
United Kingdom
PO6 3LY

Study participating centre
University Hospitals Durham
United Kingdom
DH1 5TW

Study participating centre
Royal Hampshire County Hospital
United Kingdom
SO22 5DG

Study participating centre

Hull and East Yorkshire Hospitals NHS Trust
United Kingdom
HU16 5JQ

Study participating centre
Cardiff and Vale University Health Board
United Kingdom
CF64 2XX

Study participating centre
Barnsley Hospital NHS Foundation Trust
United Kingdom
S75 2EP

Study participating centre
Poole Hospital NHS Foundation Trust
United Kingdom
BH15 2JB

Study participating centre
Ashford and St Peter's Hospitals NHS Foundation Trust
United Kingdom
KT16 0PZ

Study participating centre
Chesterfield Royal Hospital -NHS Foundation Trust
United Kingdom
S44 5BL

Study participating centre
Warrington and Halton Hospitals NHS Foundation Trust
United Kingdom
WA5 1QG

Study participating centre

Southern Health and Social Care Trust
United Kingdom
BT63 5QQ

Study participating centre
University College Hospitals London
United Kingdom
NW1 2BU

Study participating centre
South Warwickshire NHS Foundation Trust
United Kingdom
CV34 5BW

Study participating centre
University Hospital Southampton NHS Foundation Trust
United Kingdom
SO16 6YD

Study participating centre
Kettering General Hospital NHS Foundation Trust
United Kingdom
NN16 8UZ

Study participating centre
Yeovil District Hospital NHS Foundation Trust
United Kingdom
BA21 4AT

Study participating centre
Salisbury NHS Foundation Trust
United Kingdom
SP2 8BJ

Study participating centre

Torbay and South Devon NHS Foundation Trust
United Kingdom
TQ2 7AA

Study participating centre
Isle of Wight NHS Trust
United Kingdom
PO30 5TG

Study participating centre
St Georges London
United Kingdom
SW17 0QT

Sponsor information

Organisation
University of Bristol (phase 3 only)

Sponsor details
Senate House
Tyndall Ave
Bristol
England
United Kingdom
BS8 1TH

Sponsor type
University/education

Website
www.bristol.ac.uk

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

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

Funder Name
Association of Breast Surgery (pump-priming)

Funder Name
British Association of Plastic Aesthetic and Reconstructive Surgeons (pump-priming)

Results and Publications

Publication and dissemination plan
1. Several approaches will be used to disseminate the results of this study. A full report will be written for RfPB at regular intervals and the final report will be written in the last 3 months of the project
Publications
2. The work will be published in international peer-reviewed journals relevant to surgical oncologists, breast and plastic surgeons such as the Annals of Surgical Oncology, Plastic and Reconstructive Surgery and the British Journal of Surgery.
3. Oral and poster presentations at conferences
4. It will be submitted for presentation at national and international meetings (ABS, BAPRAS, ORBS) and at the Association of Surgeons in Training Conference and the National Oncoplastic Fellowship meetings to engender support for a trial among the next generation of consultant surgeons

Intention to publish date
30/05/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019	16/01/2019	Yes	No
Results article	qualitative interview results	06/04/2020	08/04/2020	Yes	No
Protocol article	protocol	04/08/2016	23/07/2020	Yes	No
Results article	results	09/07/2020	23/07/2020	Yes	No
Results article		08/01/2021	16/11/2021	Yes	No