The iBRA-2 Study
A Quick Guide for Local Study Leads

Thank you very much for agreeing to participate in the iBRA-2 study.

iBRA-2 is a multicentre prospective audit which aims to evaluate the impact of immediate breast reconstruction on the time to adjuvant therapy compared with mastectomy alone. It is hoped that the study will generate high-quality data that will help patients, surgeons and oncologists make more informed decisions about the type and timing of reconstructive surgery in the future.

We would like **ALL** breast and plastic surgical units across the UK to participate in the study so that it is a representative as possible of national practice.

We aim to collect data for **six months** between **1st July and 31st December 2016** and would like to collect data over 2000 patients.

ANY team member can be the Local Lead for the iBRA-2 study. This includes breast and plastic surgical and oncology trainees, consultants, SAS doctors, clinical nurse specialists, research staff or students. All team members who contribute at least 10 complete data sets will be PUBMED citable on study outputs. Individuals who make a lesser contribution will receive a certificate of participation for their portfolios.

The following summarises the study set-up, time-lines and processes for participating units.

Study set up – May-July 2016

- We would like participating units to be able to **commence data collection on 1st July**.
- Please register the study with your local audit department as soon as possible
- When approval is granted, please forward a copy of the approval together with the names and e-mail addresses of local collaborators who will be involved in data collection to ibrastudy@gmail.com.
- The study team will organise for REDcap access for all local collaborators on receipt of the approval confirmation

iBRA-2

Data collection – 1st July – 31st December 2016

- Eligible patients should be identified from clinics, MDTs, operating lists or other sources depending on local processes.

Inclusion criteria

- ALL patients having mastectomy for breast cancer or DCIS with or without immediate breast reconstruction are eligible to be included.
- We are interested in ALL forms of immediate reconstruction (implant-only, LD flaps, DIEPs, TUGs etc)

Exclusion criteria

- Patients having RISK-REDUCING mastectomy +/- reconstruction
- Patients not having total mastectomy (e.g. patients having volume replacement or displacement procedures following wide local excision or therapeutic mammaplasty).

Data collection time-points

Please collect data at the following time-points

1. Pre-operative (co-morbidity and neoadjuvant treatment data)
2. Operative data (1 and 2 can be collected together)
3. Post-operative MDT and pathology data
4. Post-operative complications (at 6 weeks OR until the first dose of chemotherapy/1st fraction of radiotherapy)
5. Adjuvant treatment data (date of first adjuvant treatment)

If you have any questions or queries, please e-mail us at ibrastudy@gmail.com

Many thanks for your help with the study

THE MAMMARY FOLD ACADEMIC & RESEARCH COLLABORATIVE

Royal College of Surgeons ADVANCING SURGICAL CARE

RSTN Reconstructive Surgery Trials Network