

Can patients with multiple breast cancers in the same breast avoid mastectomy by having multiple lumpectomies to achieve equivalent rates of local breast cancer recurrence?

(MIAMI feasibility RCT)

## RECENT NEWS

- ➤ NIHR Research for Patient Benefit Funding in November 2016 for the feasibility phase randomised trial, which will be the first multicentre RCT of multiple Ipsilateral breast cancers (MIBC)
- ► 5-7 UK centres participating in the feasibility study

# RANDOMIZATION DESIGN

Women will be randomly allocated in a 1:1 ratio between two arms:

#### Intervention

Multiple lumpectomies and Therapeutic Reduction Mammoplasty (Oncoplastic OBCS)

#### **Standard**

Mastectomy (+/- reconstruction)

All women will have molecular genotyping of each cancer to support the choice of chemotherapy, endocrine treatment, anti-HER-2 therapy and/or radiotherapy as part of standard care. Standard care currently comprises whole breast radiotherapy after all BCS, and clinician-selected addition of either one or two "disease site" radiotherapy boosts, mostly in women <50 years of age, with clinician-selected chest wall radiotherapy after mastectomy (30-40%).

#### **Feasibility Trial Outcomes**

These include data needed to plan the main trial accurately, ascertaining rates, compliance and outcome measures.

### Main trial primary outcome

5-year local recurrence in chest wall, retained skin or breast tissue, which is the outcome that mastectomy is designed to prevent.

#### MIAMI FLOW DIAGRAM

5 centres screening 45 new breast cancer are identified as having MIBC cancer patients per month. Each centre (n=675 with MIBC over 15 months) will screen 6 MIBC per month. Eligibility: 40% of women meet eligibility criteria ► At least one invasive cancer Largest focus ≤30mm clinically by standard imaging (including MRI) ► Two MDT surgical consensus meetings Suitable for oncoplastic BCS 30% of eligible women consent Recruitment of 2 patients per centre over to participate (n=81 potential 3 months or 1 patient per centre per month. participants) target n=50 If some centres enter the study later than others, we still expect to achieve the target of 50 participants by 15 months. Trial registration Baseline questionnaires completed RANDOMISATION **Standard Care**: Mastectomy **Intervention**: Oncoplastic Breast with/without Immediate Breast Conserving Surgery (BCS) (n=25) Reconstruction (n=25) ADJUVANT TREATMENT ADJUVANT TREATMENT Clinical follow up data at: 1,3,6 and 12 months after first surgery Clinical photographs at baseline and 12 months after first surgery Patient questionnaires at baseline, 6 and 12 months after first surgery

# TRIAL STATUS

To start in June 2017.

5–15 patients per centre over 15 months.

For further information please contact the MIAMI trial email SITU.MIAMI@ucl.ac.uk

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