MIAMI randomised trial inclusion/exclusion criteria

1.1 Inclusion criteria

1. ≥40 years with MIBC, with the largest clinical cancer measuring 30mm as part of multifocal or multicentric "disease sites". 30mm may include the size of a single cancer and its surrounding small satellite cancers (6, 7). Clinically diagnosed (ultrasound and biopsy) either axillary lymph node negative or positive where axillary treatment depends on local policy

2. Minimum of two invasive foci of breast cancer as defined within a "disease site"

3. Suitable for TM (best practice) using one large lumpectomy (multifocal) or any number of "distant" lumpectomies (multicentric) to excise "disease sites"

4. Fit for adjuvant therapy as per pre-operative evaluations (ECG, Chest X-ray, blood biochemistry)

5. Willing and able to provide written informed consent

1.2 Exclusion criteria

1. Neo-adjuvant therapy

2. Women considered high risk by local centre or known to have BRCA1/2 gene mutation

3. Ductal Carcinoma in situ (DCIS) only, and extensive DCIS

4. Bilateral breast cancers

5. Previous breast cancer (invasive or DCIS in either breast)

6. Pregnancy as confirmed on blood tests or ultrasound examination

7. Metastatic disease

8. Any previous type of breast radiotherapy

9. Significant other clinical risk factors and co-morbidities according to each centre's local policies e.g. BMI*, Diabetes, Smoker

* BMI defined as ranging from 35-40 kg/m^2, but not as an absolute exclusion, preferably to be judged by both the consultant surgeon and anaesthetist in the context of co-morbidities.

10. Previous or concomitant malignancy except adequately treated: non-melanomatous skin cancer; in situ carcinoma of the cervix and in situ melanoma