



## EXPLAINING THE BIG 2-04 MRC SUPREMO TRIAL –

### NOTES FOR CLINICIANS

**These notes aim to assist clinicians in presenting to patients the balance of potential benefits and risks of participating in the MRC SUPREMO trial. They serve as a guide only and are not in any way intended to be prescriptive.**

**Endorsement of the trial by the surgeon at the postoperative consultation with the patient is strongly recommended.**

- For patients who are at higher risk of recurrence, where there are 4 or more glands affected by breast cancer underneath the armpit or in larger cancers, a course of radiotherapy to the chest wall is routinely recommended after a mastectomy.
- For patients at intermediate risk of recurrence, where there are fewer than 4 glands involved or none involved but additional risk factors for recurrence identified in the breast tumour, the role of radiotherapy is uncertain. Practice varies. **We do not wish either to over treat or under treat patients. More research is needed. The MRC SUPREMO trial aims to answer this question.**

- **Benefits of radiotherapy**

There are potential benefits from radiotherapy in reducing the probability of recurrence of breast cancer and in improving life expectancy.

- **Side effects of radiotherapy**

Most patients will develop an acute skin reaction over the chest wall which normally settles within a few weeks of the end of treatment. **There is a very small risk of side effects affecting the ribs, lung or heart.**

#### **Clinical trials and randomisation**

In the NHS where we are uncertain whether or not a treatment is needed, there are different types of studies that can be done. **If the patient or the doctor**

**chooses the treatment, this introduces a source of bias, either from the patient's or doctor's perspective.** Any differences in the results of such studies could be due to treatment or because the patients are different. Such studies are limited value.

- The **gold standard** for assessing the effectiveness of any treatment in the NHS is a randomised clinical trial. **This provides the highest quality of evidence for advising patients on treatment.** In a randomised trial the choice of treatment is not made by the doctor or the patient but by a computer. **The advantage of this method is that it avoids any bias in the selection of the treatment. If one group of patients fares better than another, it is likely to be due to the treatment since both groups of patients have the same characteristics. This may lead to an improvement in breast cancer treatment.**

- Patients who agree to participate in the SUPREMO will have a 50% chance of receiving radiotherapy and a 50% chance of not receiving radiotherapy. However they cannot choose the treatment and have to be comfortable with whichever allocation they receive. Patients will be seen in the clinic at the same frequency whether or not they receive radiotherapy.

- **TRANS SUPREMO**

We are looking for ways **of improving the identification of patients who are likely to benefit from radiotherapy.** Normally patients are selected for radiotherapy based on factors such as the size of the cancer and the number of lymph nodes involved underneath the armpit.

- We may be able to **find genetic/biological markers in breast cancer which may more reliably predict which patients will respond to radiotherapy.** We would therefore like to seek permission to analyse a small sample of the breast cancer which has been removed from each patient and carry out a blood test on entry to the trial.

- **Quality of life**

**We have relatively little information on the impact of radiotherapy after a mastectomy on quality of life.** We are therefore inviting patients to complete a questionnaire about their quality of life before entry into the study

in the clinic and then a questionnaire sent t by post on four subsequent occasions over a period of 10 years.

- **Cardiac substudy**

Both radiotherapy and certain anti-cancer drugs can rarely have side effects on the heart. **Despite its rarity, we would like to be able to detect any damage to the heart at the earliest possible time.** We are therefore studying a protein called B-type natriuretic peptide (BNP). It is a marker of damage to the heart that we can measure in the blood. Participation would involve a series of blood tests and electrical tests of heart function (ECGs) over the period of the study and, where available, additional imaging of the heart function by passing sound waves through the heart (echocardiogram). **The advantage to patients participating in the cardiac study is the extra monitoring of heart function.**