Surgical support for OPTIMA at the multi-disciplinary team meeting is key for identifying potentially eligible patients. Whilst oncologists discuss OPTIMA in detail and consent patients, what a surgeon says to a patient about adjuvant chemotherapy is extremely important as it creates expectations. As such, surgeons set the scene for OPTIMA recruitment.

This guide summarises the study and its surgical considerations and offers tips for preparing eligible patients for a discussion about OPTIMA.

**OPTIMA Guide for Surgeons**

**Surgical considerations**

OPTIMA is an adjuvant trial; neoadjuvant treatment is not permitted. This includes endocrine therapy as this reduces the score of all multi-parameter tests.

Secondary breast surgery such as re-excision of margins or secondary mastectomy is permitted following treatment initiation including chemotherapy but all planned axillary surgery must be completed prior to trial entry. This is because axillary node status is a trial stratification factor. Axillary radiotherapy as an alternative to clearance is allowed and should take place following chemotherapy (if the patient is allocated to this).

Short term adjuvant endocrine therapy may be given pre-randomisation but the time limit for patients to join OPTIMA is 8 weeks following their final surgery.

*Rules on neoadjuvant endocrine therapy and time limit for joining the study will be relaxed in protocol version 6.*

**Talking with patients about OPTIMA**

When preparing patients for an oncology appointment it would be helpful to flag up that part of that conversation will include a discussion about a clinical study – OPTIMA. Here is a suggestion for how you might do this:

“The oncologist will talk with you about further treatment. This will include a conversation about a study (called OPTIMA) to see whether you’re likely to benefit from chemotherapy, as not all patients do.”
Please don’t say “The oncologists will arrange chemotherapy”. As you’ll have a good relationship with your patients, this creates an expectation of treatment and it can then be difficult to introduce the study concept and the idea that they may not get chemotherapy.

We have produced a patient flyer to introduce and prepare patients for a fuller discussion with an oncologist about OPTIMA. The flyer is in addition to the patient information sheet. We ask that you or your breast care nurse hand out the flyer at post-surgical clinic appointments to patients flagged by the MDT as potentially eligible.

**OPTIMA Study Design**

**Eligibility**
Female or Male, age ≥ 40
Excised primary breast cancer, ER+ve, HER2–ve (local pathology)
\( pN1-2 \ OR \ pN1mi \ & \ pT \geq 20mm \ OR \ pN0 \ & \ pT \geq 30mm \)

**Consent & Registration**
Tumour block sent to central lab

GROUP 1: Control arm
\( n=2250 \)

GROUP 2: Test directed arm
\( n=2250 \)

**Prosigna test**
- Low Prosigna Score: ≤60
- High Prosigna Score: >60

Treatment assigned by test score

**Randomisation**
Blinded

High Score
Chemotherapy
Endocrine therapy
Follow up for 10 years

Low Score
Chemotherapy
Endocrine therapy

Primary outcomes = Treatment outcome for Group 2 not worse than Group 1 (“IDFS - \( \Delta=-3\% \))

Cost effectiveness evaluation of test-directed treatment

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