

The OPTIMA Guide for Breast Nurse Specialists



Breast Nurse Specialists and OPTIMA

OPTIMA is a randomised controlled trial designed to find out if a multi-parameter test can effectively and safely identify if a patient is likely to benefit from adjuvant chemotherapy or not. OPTIMA uses the Prosigna test.

Recruitment to OPTIMA is a team activity relying on: surgeons, breast nurse specialists, pathologists, oncologists, research nurses and trial co-ordinators.

Breast nurse specialists build trusting relationships with patients and often patients will look to them for guidance about what will happen following surgery. What you and your surgical colleagues say to a patient about adjuvant treatment, can shape patient expectations and in turn, recruitment to OPTIMA.

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

The Study

OPTIMA aims to identify patients most likely to benefit from chemotherapy and those who may be better treated by moving directly to hormone therapy.

OPTIMA expects to recruit mostly patients with node-positive (including micrometastatic) disease because this is where there is greatest uncertainty. Node-negative patients can participate if Oncotype DX or other tests are not used.

Multi-Disciplinary Teams will identify patients with ER-positive HER2-negative early breast cancer that would ordinarily be treated with chemotherapy and who meet the eligibility criteria. Oncologists will explain the study to eligible patients and invite them to join OPTIMA.

OPTIMA randomises eligible participants between standard treatment (chemotherapy followed by endocrine therapy) or to have a Prosigna test performed on the tumour. If the tumour has a high Prosigna Score (>60) then the patient will be assigned

to standard treatment whilst those with a lower score receive endocrine therapy only. Patients receiving chemotherapy are blinded to the reason (randomised to control arm or high Prosigna test score). An estimated two thirds of patients whose tumours are tested will avoid chemotherapy.

The Prosigna test is performed on fixed tissue in a UK-based lab. The test takes less than 2 weeks from consent for the majority of patients. See the diagram overleaf for more information on study design.

Introducing OPTIMA to Patients

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 avoid presenting chemotherapy as a definite as this can create an expectation of treatment. It may then be difficult for the oncologist to introduce the study concept and the idea that they may not get chemotherapy.

OPTIMA Patient Information Flyer

Have you just had surgery for breast cancer?

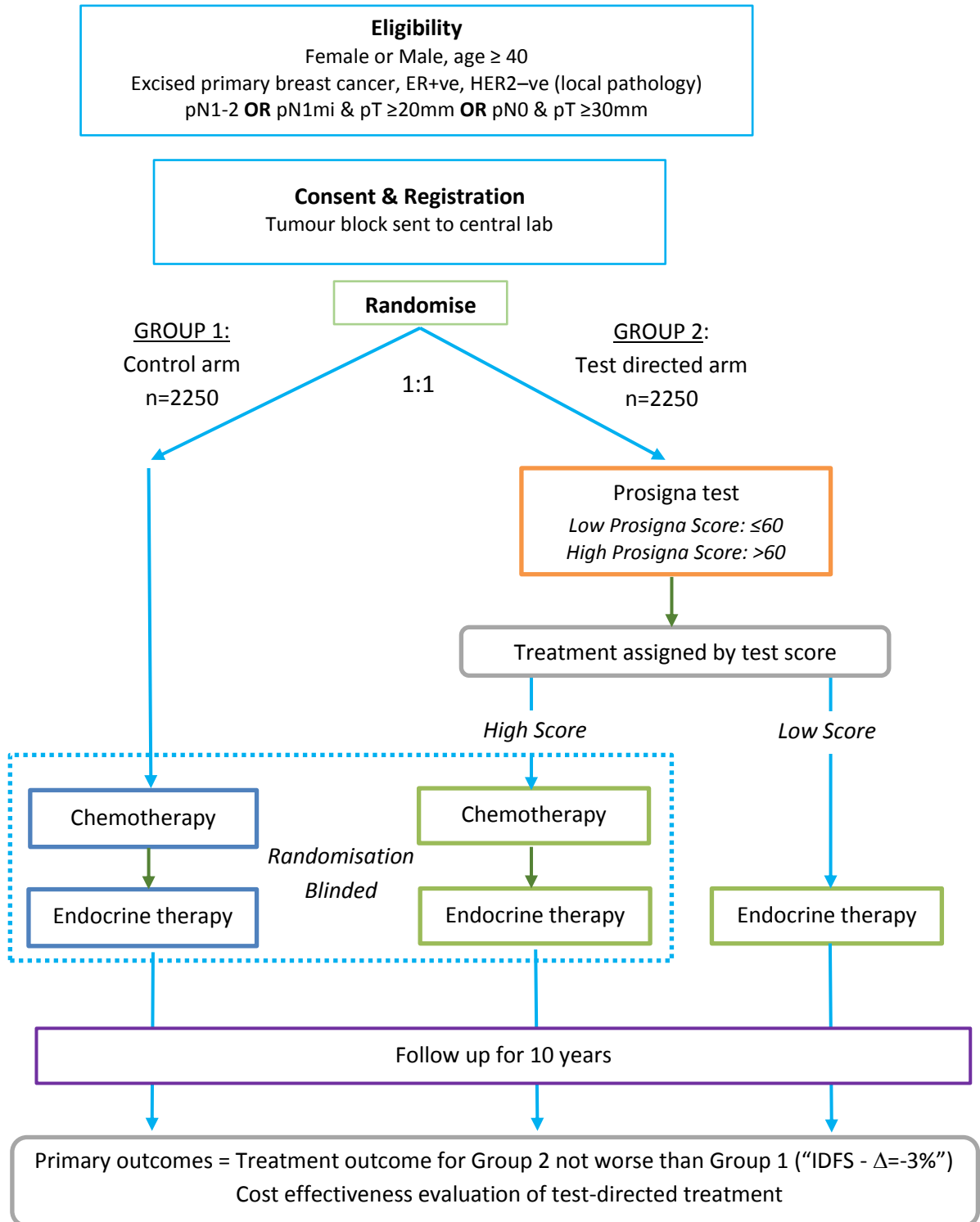
You might be suitable for OPTIMA



Working with patients, the OPTIMA team have produced a patient information 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 hand it out at post-surgical appointments to patients flagged by the MDT as potentially eligible for OPTIMA.

OPTIMA Study Design



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