The OPTIMA Trial: Surgeon Guide

Surgeons and the OPTIMA Study

OPTIMA is a large randomised trial designed to improve chemotherapy decision making for patients with high clinical risk ER positive breast cancer.

We know that surgeons play a major role in OPTIMA recruitment from analysis of recorded consultations and interviews with eligible patients.

Many patients first hear about adjuvant treatment and OPTIMA from their surgeon. These early conversations can shape what a patient goes on to think about OPTIMA, given the strong relationship between surgeons and their patients.

Introducing OPTIMA to eligible patients

We would like your help in preparing patients for a detailed discussion about OPTIMA. You can best do this by introducing adjuvant treatment without indicating whether this will or will not include chemotherapy.

It is really important to avoid setting patient expectations by saying *"The oncologist will arrange chemotherapy"* or *"You will only need radiotherapy and hormone therapy".* Comments like these can lead to a patient anticipating a particular treatment ahead of a full discussion and make it difficult for an eligible patient to consider joining OPTIMA.

One way of introducing OPTIMA might be to say something like:

"The oncologist is going to talk with you about further treatment. This may or may not include chemotherapy and they will be discussing a study (called OPTIMA) to see whether you're likely to benefit from chemotherapy, as not all patients do."

We have produced a patient flyer and an animated video to prepare eligible patients for a detailed discussion. At the post-surgical visit it would be very helpful if you could:

- hand out the OPTIMA patient flyer
- invite patients to watch the animation at: optimabreaststudy.com
  (There is a QR code on the flyer.)

The OPTIMA Study

The trial is described in more detail overleaf. Patients are randomised between chemotherapy for all (standard treatment) or test-directed chemo-therapy. All patients have endocrine therapy.

Two thirds of patients in the investigational arm avoid chemotherapy.

The Prosigna test is performed in a UK lab and takes less than 2 weeks.

OPTIMA is a pragmatic study that accommodates local practice. Patients may join other trials.

Whilst mostly recruiting patients with node-positive disease, node-negative patients with large tumours are eligible.

Surgical Considerations

- Up to eight weeks of neoadjuvant endocrine therapy may be given.
- Neoadjuvant chemotherapy is not permitted.
- All planned axillary surgery must be completed before trial entry. (This avoids any change to axillary status after randomisation).
- Axillary radiotherapy is allowed as an alternative to clearance with no time limit.

Completion breast surgery (re-excision or mastectomy) is permitted after trial entry.

Why OPTIMA is Important

Tumour gene tests are approved for patients with node-negative disease. Important knowledge gaps about the tests remain.

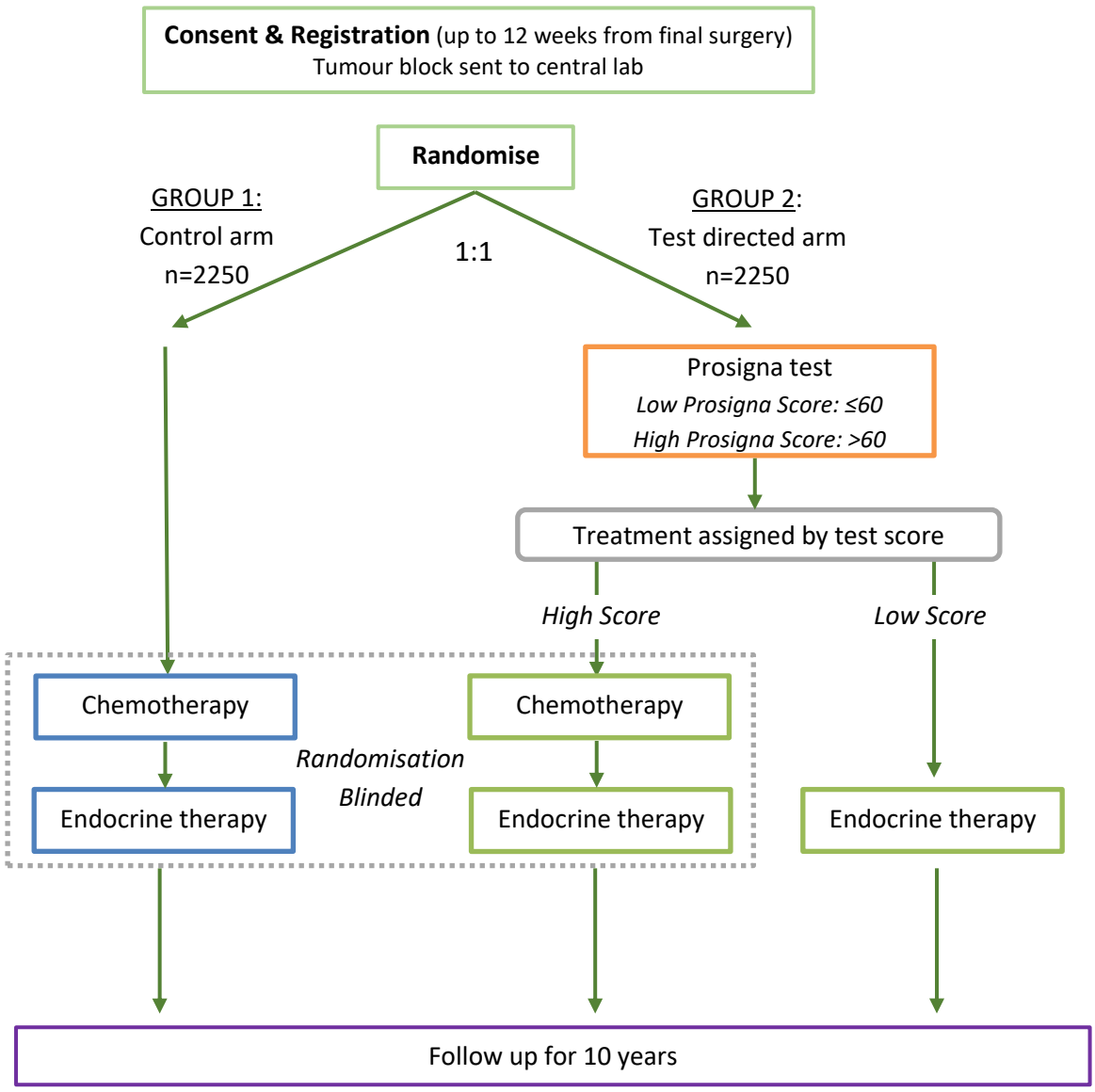
- There is still no robust evidence that the tests are safe in patients with 1-3 involved nodes. Only a small minority of patients in existing trials had high grade disease, or more than one involved node.
- There is no data for patients with 4 or more nodes.
- Very few patients with large node-negative tumours were included in supporting trials.
- No trial yet has controlled for chemotherapy effects on ovarian function. This may explain why the tests perform less well in younger women.

OPTIMA will fill in important knowledge gaps

Version 2.0 25 October 2021

Eligibility

- Female or Male, age ≥ 40
- Excised primary breast cancer
- ER+ve, HER2–ve
- Size and node status - one of
  - pN1-2
  - pN1mi & pT ≥20mm
  - pN0 & pT ≥30mm
- Multifocal & some bilateral tumours permitted
- Up to 8 weeks neoadjuvant ET
- Early commencement post-operative ET permitted
- Delayed completion of breast surgery permitted



Contact: OPTIMA Trial Office, T 02476 151 057, E optima@warwick.ac.uk

Scan to view the OPTIMA introductory animation