OPTIMA: Optimal Personalised Treatment of early breast cancer usIng Multi-parameter Analysis

Record Status
This is a bibliographic record of an ongoing health technology assessment being undertaken by a member of INAHTA. Links to the published report and any other relevant documentation will be added when available.

Citation
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Authors’ objectives
Breast cancer deaths have fallen over the last 30 years from around half of all cases diagnosed to about a quarter due to post-surgical radiotherapy, endocrine treatment and chemotherapy. But, clinicians are concerned that many patients (especially those with the commonest ER-positive cancers) don’t benefit from chemotherapy and are being exposed unnecessarily to unpleasant side effects. The clinician’s dilemma is knowing who will benefit from chemotherapy and who can be safely spared. The OPTIMA trial will look at improving the selection of those patients who may benefit from chemotherapy using a test to determine who will have chemotherapy. These so called multi-parameter tests measure the activity of up to 100 genes in a tumour sample that are important in breast cancer to predict the risk of cancer recurrence. NICE evaluated four multi-parameter tests from 2011-13 and recommended that one (Oncotype DX) be made available for some NHS patients; NICE thought extra research was required on the other three. There is evidence that multi-parameter tests can also predict chemotherapy sensitivity but NICE considered that more research was needed on this topic. This question will be answered by OPTIMA. The OPTIMA trial will involve 4500 patients to look at the value of multi-parameter tests in the NHS. OPTIMA prelim, the feasibility study for the main trial, demonstrated that such a trial is possible and that patients can be recruited. The OPTIMA patient population will be at higher risk of relapse than those in the NICE evaluation because most will have cancer in their under-arm (axillary) lymph nodes. These patients are not eligible for NHS-funded Oncotype DX testing and would routinely be offered chemotherapy in addition to five or more years of endocrine therapy even if they may not benefit from the chemotherapy. Patients who consent to the trial will be randomised to standard management or to the test-directed treatment arm in which they will be assigned treatment (endocrine therapy with or without chemotherapy) according to the result of a Prosigna test performed on tumour tissue. Patients receiving chemotherapy will not know if they are on standard or test-directed treatment. Patients will be asked to donate spare tumour tissue for future research into gene tests. The main test used in OPTIMA prelim was Oncotype DX but other tests were evaluated to see which might offer the greatest value to the NHS. The value of Prosigna was shown to be higher than for the other tests, so this test will be used in the main OPTIMA trial. This is the biggest design change from OPTIMA prelim. Patients from OPTIMA prelim will be included in the final analysis. In order to show that test-directed treatment is safe, OPTIMA will compare the number of patients whose cancer returns within five years according to how their treatment was decided. The trial hypothesis is that there will be no more cancer recurrence with test-directed treatment compared with standard management. If this happens, OPTIMA will have shown that it is safe to use multi-parameter tests to make decisions about chemotherapy. The cost-effectiveness to the NHS of treating patients with chemotherapy in OPTIMA will be measured using information about the treatment given to patients collected from hospitals, questionnaires about the effect of treatment on family finance given to patients and information about long-term health of participants collected from central NHS databases.

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