OPTIMA prelim: a randomised feasibility study of personalised care in the treatment of women with early breast cancer

Stein RC, Dunn JA, Bartlett JMS, Campbell AF, Marshall A, Hall P, Rooshenas L, Morgan A, Poole C, Pinder SE, Cameron DA, Stallard N, Donovan JL, McCab

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Citation

Authors' objectives
There is uncertainty about the chemotherapy sensitivity of some oestrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancers. Multiparameter assays that measure the expression of several tumour genes simultaneously have been developed to guide the use of adjuvant chemotherapy for this breast cancer subtype. The assays provide prognostic information and have been claimed to predict chemotherapy sensitivity. There is a dearth of prospective validation studies. The Optimal Personalised Treatment of early breast cancer using Multiparameter Analysis preliminary study (OPTIMA prelim) is the feasibility phase of a randomised controlled trial (RCT) designed to validate the use of multiparameter assay directed chemotherapy decisions in the NHS. OPTIMA prelim was designed to establish the acceptability to patients and clinicians of randomisation to test-driven treatment assignment compared with usual care and to select an assay for study in the main RCT.

Authors' conclusions
OPTIMA prelim has achieved its aims of demonstrating that a large UK clinical trial of multiparameter assay-based selection of chemotherapy in hormone-sensitive early breast cancer is feasible. The economic analysis shows that a trial would be economically worthwhile for the NHS. Based on the outcome of the OPTIMA prelim, a large-scale RCT to evaluate the clinical effectiveness and cost-effectiveness of multiparameter assay-directed chemotherapy decisions in hormone-sensitive HER2-negative early breast would be appropriate to take place in the NHS.

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Address for correspondence
NETSCC, Health Technology Assessment, Alpha House, University of Southampton Science Park, Southampton, SO16 7NS UK Tel: +44 23 8059 5586 Email: hta@hta.ac.uk

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