tAnGo

Paclitaxel, Anthracycline, Gemcitabine, Cyclophosphamide

A phase III randomised trial of gemcitabine in paclitaxel-containing, epirubicin-based, adjuvant chemotherapy for ER/PgR-poor, early stage, breast cancer

PRIMARY OBJECTIVE

To examine whether the addition of gemcitabine to the second phase of a control regimen of epirubicin and cyclophosphamide followed by paclitaxel improves disease-free survival in relation to epirubicin and cyclophosphamide followed by paclitaxel alone, in women presenting with higher risk, early stage ER/PgR-poor breast cancer

TRIAL DESIGN

A randomised, phase III, International, multi-centre, two arm trial

OUTCOME MEASURES

Primary

- 5-year disease-free survival

Secondary

- 5 and 10-year overall survival
- 10-year disease-free survival
- Toxicity, dose intensity and tolerability
- Serious Adverse Events

Sub-studies

Quality Of Life

- Assessing Quality of Life in a 500+ Patient cohort

Detailed Safety Study

- To assess the safety and tolerability of adding Gemcitabine

Translational Study

- Independent Molecular profiling and candidate gene analysis on paraffin-embedded tumours

SAMPLE SIZE

3152 Patients

MAIN SELECTION CRITERIA

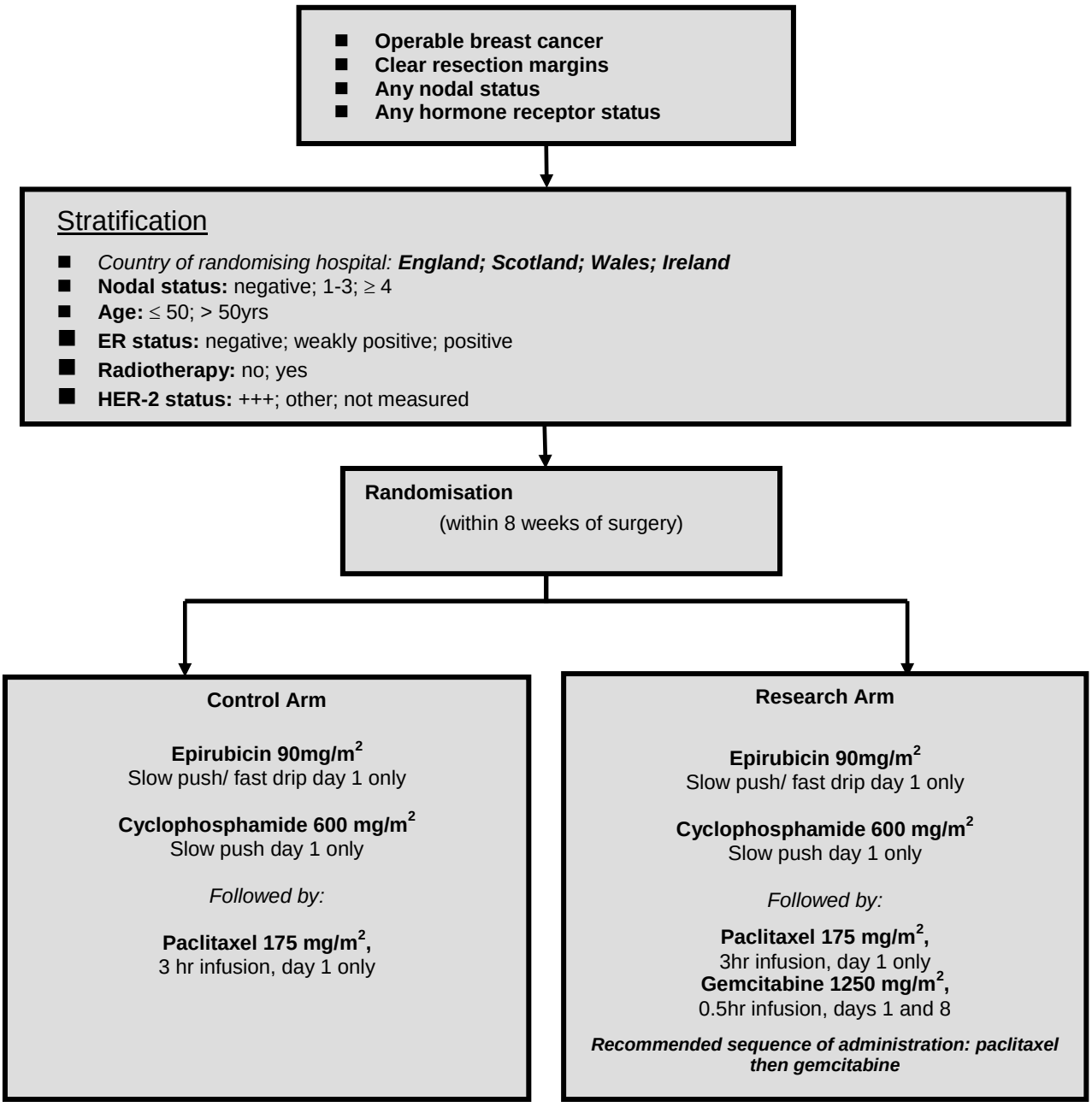
- Women with completely excised, newly diagnosed, early stage breast cancer
- Definite indication for adjuvant chemotherapy
- Any nodal status
- Tumour is ER-negative/weakly positive **or** both ER-positive *and* PgR-negative/weakly positive
- Adequate marrow, hepatic and renal function
- 18 years or older, with an ECOG performance status of 0, 1, or 2
- No prior chemotherapy
- No prior radiotherapy
- No evidence of metastatic spread
- Not Pregnant or lactating

UNIVERSITY OF CAMBRIDGE

CANCER RESEARCH UK

THE UNIVERSITY OF BIRMINGHAM

TRIAL SCHEMA



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