Articles

Fulvestrant 500 mg versus anastrozole 1 mg for hormone receptor-positive advanced breast cancer (FALCON): an international, randomised, double-blind, phase 3 trial

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Summary

Background

Aromatase inhibitors are a standard of care for hormone receptor-positive locally advanced or metastatic breast cancer. We investigated whether the selective oestrogen receptor degrader fulvestrant could improve progression-free survival compared with anastrozole in postmenopausal patients who had not received previous endocrine therapy.

Methods

In this phase 3, randomised, double-blind trial, we recruited eligible patients with histologically confirmed oestrogen receptor-positive or progesterone receptor-positive, or both, locally advanced or metastatic breast cancer from 113 academic hospitals and community centres in 20 countries. Eligible patients were endocrine therapy-naive, with WHO performance status 0–2, and at least one measurable or non-measurable lesion. Patients were randomly assigned (1:1) to fulvestrant (500 mg intramuscular injection; on days 0, 14, 28, then every 28 days thereafter) or anastrozole (1 mg orally daily) using a computer-generated randomisation scheme. The primary endpoint was progression-free survival, determined by Response Evaluation Criteria in Solid Tumors version 1·1, intervention by surgery or radiotherapy because of disease deterioration, or death from any cause, assessed in the intention-to-treat population. Safety outcomes were assessed in all patients who received at least one dose of randomised treatment (including placebo). This trial is registered with ClinicalTrials.gov, number NCT01602380.

Findings

Between Oct 17, 2012, and July 11, 2014, 524 patients were enrolled to this study. Of these, 462 patients were randomised (230 to receive fulvestrant and 232 to receive anastrozole). Progression-free survival was significantly longer in the fulvestrant group than in the anastrozole group (hazard ratio [HR] 0·797, 95% CI 0·637–0·999, p=0·0486). Median progression-free survival was 16·6 months (95% CI 13·83–20·99) in the fulvestrant group versus 13·8 months (11·99–16·59) in the anastrozole group. The most common adverse events were arthralgia (38 [17%] in the fulvestrant group *vs* 24 [10%] in the anastrozole group) and hot flushes (26 [11%] in the fulvestrant group *vs* 24 [10%] in the anastrozole group). 16 (7%) of 228 patients in in the fulvestrant group and 11 (5%) of 232 patients in the anastrozole group discontinued because of adverse events.

Interpretation

Fulvestrant has superior efficacy and is a preferred treatment option for patients with hormone receptor-positive locally advanced or metastatic breast cancer who have not received previous endocrine therapy compared with a third-generation aromatase inhibitor, a standard of care for first-line treatment of these patients.

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