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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Introduction

First-line treatment recommendations for post-menopausal women with hormone receptor-positive (oestrogen receptor or progesterone receptor, or both) locally advanced or metastatic breast cancer includes endocrine therapy with a third-generation aromatase inhibitor (anastrozole, letrozole, or exemestane) or tamoxifen.[1–3] In hormone receptor-positive disease, third-generation aromatase inhibitors have increased efficacy compared with tamoxifen in terms of time to progression.[4–8]

Fulvestrant, a selective oestrogen receptor degrader that blocks oestrogen receptor function by inducing oestrogen receptor degradation,[9] is approved for postmenopausal women with hormone receptor-positive advanced breast cancer and disease progression after anti-oestrogen therapy.[10,11] The 500 mg dose of fulvestrant was approved based on data from the phase 3, double-blind Comparison of Faslodex in Recurrent or Metastatic Breast Cancer (CONFIRM)[12] study that compared fulvestrant 500 mg with fulvestrant 250 mg in patients with hormone receptor-positive advanced breast cancer who had progression after endocrine therapy. In CONFIRM, progression-free survival (hazard ratio [HR] 0·80, 95% CI 0·68–0·94; p=0·006)[12] and overall survival (HR 0·81, 0·69–0·96; p=0·02)[13] were increased with fulvestrant 500 mg versus fulvestrant 250 mg.

Improved efficacy of first-line treatment with fulvestrant compared with anastrozole was shown in the phase 2, open-label Fulvestrant First-Line Study

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Research in context

Evidence before this study

We did a general search on PubMed and ClinicalTrials.gov using the search terms "fulvestrant 500 mg" and "clinical trial" to identify clinical studies of fulvestrant 500 mg, a selective oestrogen receptor degrader, versus any third-generation aromatase inhibitor. No date or language limitations were applied. A previous open-label, phase 2 study (FIRST) in postmenopausal women with hormone receptor-positive locally advanced or metastatic breast cancer, most of whom were endocrine-naive, showed that first-line fulvestrant was at least as effective as anastrozole in terms of clinical benefit rate and was superior in terms of time to progression and overall survival. We identified no phase 3, double-blind trials comparing fulvestrant with anastrozole in hormone receptor-positive postmenopausal women with advanced breast cancer who have not received previous endocrine treatment.

Added value of the study

To our knowledge, the FALCON study is the first randomised, double-blind, multicentre trial to assess the efficacy and safety of fulvestrant compared with anastrozole in hormone receptor-positive postmenopausal women with advanced breast cancer who have not received previous endocrine treatment—a clinically meaningful patient population. Results from our study therefore add to the extensive data for the efficacy and safety of fulvestrant in patients with advanced breast cancer and consolidate evidence for superior efficacy for fulvestrant compared with anastrozole shown in FIRST.

Implications of all the available evidence

The results of the FALCON study support the notion that a selective oestrogen receptor degrader is a more efficacious treatment than a third-generation aromatase inhibitor, which is the standard-of-care in first-line endocrine therapy for patients with hormone receptor-positive advanced breast cancer. These findings consolidate the known clinical effectiveness of fulvestrant and support the use of fulvestrant monotherapy in endocrine-naive patients with hormone receptor-positive advanced breast cancer.

Comparing Endocrine Treatments (FIRST)[14] in postmenopausal women with hormone receptor-positive locally advanced or metastatic breast cancer. Fulvestrant was shown to be at least as effective as anastrozole in terms of clinical benefit rate (74 [73%] of 102 with fulvestrant *vs* 69 [67%] of 103 with anastrozole; odds ratio [OR] 1·30, 95% CI 0·72–2·38, p=0·386).[14] In subsequent follow-up analyses, fulvestrant was associated with a longer progression-free survival/time to progression than anastrozole (HR 0·66, 95% CI 0·47–0·92, p=0·01)[15] and improved overall survival compared with anastrozole (HR 0·70, 0·50–0·98, p=0·04).[16]

In the Fulvestrant and Anastrozole Compared in Hormonal Therapy Naive Advanced Breast Cancer (FALCON) trial, we aimed to assess the progression-free survival advantage for fulvestrant versus anastrozole observed in the FIRST study. The population for FALCON were postmenopausal women with hormone receptor-positive locally advanced or metastatic breast cancer who had not received previous endocrine therapy to avoid reducing efficacy of the control group through exposure to adjuvant endocrine therapy.

See Online for appendix

Methods

Study design and participants

In this phase 3, randomised, double-blind, double-dummy international trial, we compared the efficacy and tolerability of fulvestrant with anastrozole in postmenopausal women with histologically confirmed hormone receptor-positive (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 in Asia, Europe, North America, South America, and South Africa.

Eligible patients were postmenopausal women who had a WHO performance status of 0–2, and one or more measurable or non-measurable lesion. Key exclusion criteria were previous hormonal treatment for breast cancer; presence of life-threatening, metastatic visceral disease; previous systemic therapy for breast cancer, except one line of cytotoxic chemotherapy; radiotherapy if completed within 28 days before randomisation (unless for bone pain control); human epidermal growth factor receptor over-expression or gene amplification; concomitant anticancer treatment (except bisphosphonates or denosumab); or systemic oestrogen-containing hormone-replacement therapy use within 6 months before randomisation (appendix).

The study was done in accordance with the Declaration of Helsinki and International Conference on Harmonisation and Good Clinical Practice guidelines. An ethics committee or institutional review board approved the final protocol at each study site. All patients provided written, informed consent.

Randomisation and masking

Patients were randomly assigned (1:1) sequentially to receive either fulvestrant 500 mg or anastrozole 1 mg using a computer-generated randomisation scheme and an integrated voice or web response system. Patients were stratified at randomisation according to locally advanced or metastatic breast cancer; previous or no previous treatment with chemotherapy for locally advanced or metastatic breast cancer; and measurable or non-measurable disease. Study drugs were labelled using

a unique identifier linked to the randomisation scheme. Neither participants nor investigators (including those assessing outcomes) were aware of treatment assignment. The active study drug and placebo for fulvestrant (prefilled syringes) and anastrozole (tablets) were identically packaged to maintain blinding.

Procedures

Study treatment was initiated at randomisation (day 0). Fulvestrant 500 mg (plus daily anastrozole placebo) was administered on days 0, 14 (plus or minus 3 days), 28 (plus or minus 3 days), and every 28 (plus or minus 3 days) days thereafter as two 5 mL intramuscular injections at each visit. No fulvestrant dose reductions were permitted. Anastrozole (plus fulvestrant placebo on days 0, 14, 28, and every 28 days thereafter) was administered once daily as a single tablet. Treatment continued until objective disease progression or other criteria for discontinuation were met in terms of adverse events, protocol non-adherence, or patient's decision to withdraw.

Study visits occurred at screening (within 28 days before randomisation), randomisation (day 0), day 14, every 4 weeks from week 4 to week 24, and every 12 weeks thereafter until disease progression. Safety and tolerability were assessed at each study visit, and for up to 8 weeks after the last fulvestrant or placebo injection. Health-related quality of life questionnaires[17] were administered at baseline and every 3 months thereafter. After disease progression or treatment discontinuation, health-related questionnaires will be administered every 6 months until a final overall survival analysis.

Outcomes

The primary endpoint of the study was progression-free survival of patients treated with fulvestrant versus anastrozole. A progression event was determined based on tumour assessments done locally by each investigator and was defined by Response Evaluation Criteria in Solid Tumors version 1·1, or surgery or radiotherapy for worsening of disease, or death from any cause.

Secondary endpoints included objective response rate (best overall response of either complete response or partial response in patients with measurable disease at baseline), duration of response, and expected duration of response, clinical benefit rate (best overall response of complete response, partial response, or stable disease ≥24 weeks), duration of clinical benefit, expected duration of clinical benefit, and overall survival (time from randomisation until death by any cause).

Health-related quality of life was assessed using the Trial Outcome Index derived from the Functional Assessment of Cancer Therapy for Breast Cancer (FACT-B) questionnaire,[17] and FACT-B total score.

Safety and tolerability assessments included adverse events (graded according to Common Terminology Criteria for Adverse Event [CTCAE], version 4·0), serious adverse events, discontinuations because of adverse events, deaths because of adverse events, and predefined adverse events of special interest (joint disorders and back pain). Laboratory variables, electrocardiogram recordings, physical examination, and vital signs were monitored at prespecified timepoints throughout the study.

Statistical analysis

For the primary outcome, progression-free survival was assessed at a single timepoint when approximately 306 progression events had occurred. Randomisation of approximately 450 patients was planned to achieve 306 progression events. The HR of 0·69 was considered to be a reasonable estimate of the true HR in the FALCON population based on results from a phase 2 study.[14,15] If 0·69 was the true progression-free survival HR for the comparison of fulvestrant with anastrozole, then 306 events was calculated to provide 90% power for statistical significance at the 5% two-sided level. A progression-free survival HR of 0·80 would deliver a statistically significant difference for the primary outcome. The primary analysis for this study was done in the intent-to-treat population comprising all randomly assigned patients. All safety outcomes were assessed in all patients who received at least one dose of randomised treatment (including placebo) according to the actual treatment initially received.

Comparison of progression-free survival for fulvestrant versus anastrozole was done using a stratified log-rank test at the two-sided 5% significance level in the intention-to-treat population. Strata included were previous chemotherapy for locally advanced or metastatic disease and measurable disease; locally advanced versus metastatic disease was not included because only a small number of patients had locally advanced disease. Results are presented as an estimate of the HR, associated 95% CI, and p value. An interim analysis of overall survival was done at the time of progression-free survival analysis, and overall survival was analysed in the same way as progression-free survival. Overall survival and objective response rate were tested with a multiple testing procedure with an α-exhaustive recycling strategy to control type I error at the overall α level.[18] Clinical benefit rate was analysed with a logistic regression model including the same stratification factors as for progression-free survival and examination of the OR of the two treatment groups. Objective response rate was analysed in the same way as clinical benefit rate; however, measurable disease was not included in the model. Kaplan-Meier plots were produced for duration of clinical benefit and duration of response. Expected duration of clinical benefit and expected duration of response are designed to provide an unbiased treatment comparison of duration of clinical benefit and duration of response by including all randomly assigned patients (rather than only responding patients) and were calculated using the method described by Ellis and colleagues.[19] Expected

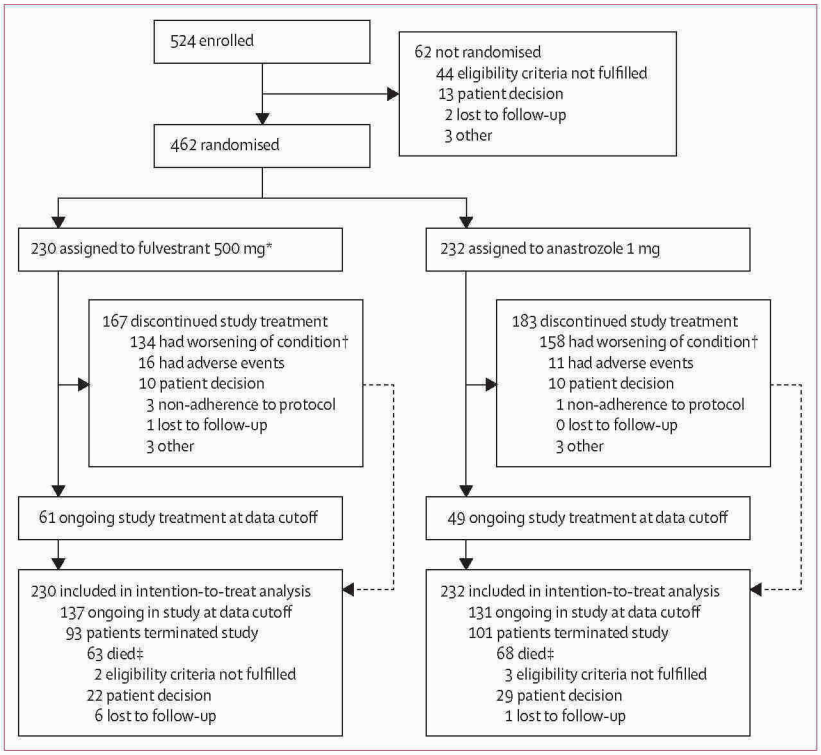

Figure 1: **Trial profile**
*Two patients in the fulvestrant 500 mg group did not receive treatment (patient decision). †Includes patients with disease progression. ‡Deaths exclude patients who terminated the study for other reasons (four patients in the fulvestrant group and seven patients in the anastrozole group) but were subsequently found to have died.

duration of response and expected duration of clinical benefit allow a statistical comparison to be made on the duration of response and clinical benefit between the two treatment groups. An analysis of time to deterioration of Trial Outcome Index and FACT-B total score was done as described for progression-free survival.

A subgroup analysis was done on progression-free survival data in the intention-to-treat population for the following baseline covariates: oestrogen receptor-positive and progesterone receptor-positive (yes or no), metastatic disease (yes or no), concomitant use of bisphosphonates (yes or no), measurable disease (yes or no), previous chemotherapy for locally advanced or metastatic breast cancer (yes or no), geographic region, previous systemic oestrogen containing hormone replacement therapy (yes or no), and visceral disease (yes or no). HRs and 95% CI were calculated, and a Kaplan-Meier was generated for each subgroup. A global interaction test was done with a Cox-proportional hazard model to assess whether the treatment effect was consistent across the covariates. A post-hoc interaction test to assess for consistency of the treatment effects across the visceral and non-visceral subgroups was also done. Adverse events were summarised descriptively using the Medical Dictionary for Regulatory Activities preferred terms. SAS versions 9.2 and 9.4 were used for statistical analyses. This trial is registered with ClinicalTrials.gov, number NCT01602380.

Role of the funding source
The funder of the study was involved in study design, reviewing and interpreting the data, and writing the manuscript. The funder of the study reviewed the manuscript before submission to ensure medical and scientific accuracy and for protection of intellectual property. All authors were involved in data analysis and interpretation, manuscript writing, and approved the final manuscript. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between Oct 17, 2012, and July 11, 2014, 524 patients were enrolled to this study. Of these, 462 patients were randomly assigned and make up the intention-to-treat population (230 to the fulvestrant group and 232 to the anastrozole group; figure 1). Data cutoff was April 11, 2016, when the target number of progression-free survial events (306) was expected to have been met. Two patients in the fulvestrant group did not receive study treatment after randomisation (patient decision); therefore, the safety population had 228 patients in the fulvestrant group and 232 patients in the anastrozole group.

14 protocol deviations related to eligibility criteria were observed in both the fulvestrant and anastrozole groups. Three patients were reported to have received previous endocrine therapy. These protocol deviations were considered unlikely to affect the interpretation of study data. Baseline demographic and disease characteristics were generally well balanced between groups (table 1).

There were 309 progression events at data cutoff. Of these, 143 (62%) of 230 occurred in the fulvestrant group and 166 (72%) of 232 occurred in the anastrozole group. Fulvestrant was associated with a statistically significant improvement in progression-free survival compared with anastrozole (HR 0·797, 95% CI 0·637–0·999, p=0·0486; figure 2). Median progression-free survival was 16·6 months (95% CI 13·83–20·99) with fulvestrant and 13·8 months (11·99–16·59) with anastrozole (difference in medians: 2·8 months).

In patients with measurable disease, the objective response rate was 46% (89/193) with fulvestrant and 45% (88/196) with anastrozole (OR 1·07, 95% CI 0·72–1·61, p=0·7290). Duration of response in patients with measurable disease at baseline is shown in the appendix. Median duration of response was longer in the fulvestrant group (20·0 months [95% CI 15·90–27·63]) than in the anastrozole group (13·2 months [95% CI 10·64–16·72]). Expected duration of response was 11·4 months in the fulvestrant group and 7·5 months in the anastrozole group (expected duration of response ratio 1·52, 95% CI 1·03–2·26, p=0·0367).

Clinical benefit rate was 78% (180/230) with fulvestrant and 74% (172/232) with anastrozole (OR 1·25, 95% CI 0·82–1·93, p=0·3045; table 2). Duration of clinical benefit in patients with clinical benefit is shown in the

	Fulvestrant 500 mg (n=230)	Anastrozole 1 mg (n=232)
Age (years)	64·0 (38–87)	62·0 (36–90)
Patients aged ≥65 years	108 (47%)	91 (39%)
Race		
White	175 (76%)	174 (75%)
Asian	36 (16%)	34 (15%)
Black or other	19 (8%)	24 (10%)
Time from diagnosis of breast cancer to randomisation		
≤2 months	102 (44%)	99 (43%)
>2 months to ≤1 year	58 (25%)	66 (28%)
>1 year	70 (30%)	67 (29%)
Receptor status		
Oestrogen receptor positive, progesterone receptor positive	175 (76%)	179 (77%)
Oestrogen receptor positive, progesterone receptor negative	44 (19%)	43 (19%)
Oestrogen receptor positive, progesterone receptor unknown	10 (4%)	7 (3%)
Oestrogen receptor negative, progesterone receptor positive	1 (<1%)	3 (1%)
Oestrogen receptor negative, progesterone receptor negative	0	0
Human epidermal growth factor receptor status		
Positive	0	1 (<1%)
Negative	230 (100%)	231 (100%)
WHO performance status*		
0	117 (51%)	115 (50%)
1	106 (46%)	105 (45%)
2	7 (3%)	12 (5%)
Disease stage		
Locally advanced	28 (12%)	32 (14%)
Metastatic	202 (88%)	200 (86%)
Site of disease		
Visceral disease†	135 (59%)	119 (51%)
Bone or musculoskeletal only	24 (10%)	24 (10%)
Breast only	3 (1%)	2 (1%)
Skin or soft tissue only	8 (3%)	6 (3%)
Other non-visceral	60 (26%)	81 (35%)
Measurable disease	193 (84%)	196 (84%)
Previous treatment‡		
Chemotherapy		
Locally advanced or metastatic breast cancer§	36 (16%)	43 (19%)
Adjuvant	35 (15%)	27 (12%)
Neoadjuvant	11 (5%)	16 (7%)
Radiotherapy	53 (23%)	50 (22%)
Immunotherapy	0	0
Hormonal therapy	2 (1%)	1 (<1%)

(Table 1 continues in next column)

(Table continued from previous column)

Data are median (range) and n (%). *For WHO performance status, 0 represents normal activity, 1 represents restricted activity, and 2 represents being in bed 50% of the time or less. †Includes patients with site of baseline disease as any of the following: adrenal, bladder, CNS, oesophagus, liver, lung, peritoneum, pleura, renal, small bowel, stomach, pancreas, thyroid, colon, rectal, ovary, biliary tract, ascites, pericardial effusion, spleen, or pleural effusion. ‡Previous enrolment categories are not mutually exclusive. §Includes first-line, second-line, third-line, metastatic, and palliative chemotherapies (two patients were reported as deviations for having received second-line chemotherapy and one patient was reported in error to have received three previous lines of chemotherapy).

Table 1: **Patient baseline demographics and disease characteristics of the intention-to-treat population**

appendix. The median duration of clinical benefit was 22·1 months (95% CI 18·46–24·87) with fulvestrant and 19·1 months (16·53–20·47) with anastrozole. The expected duration of clinical benefit was 21·9 months in the fulvestrant group and 17·5 months in the anastrozole group (expected duration of clinical benefit ratio 1·26, 95% CI 0·99–1·59, p=0·0561). Median overall survival could not be calculated because of insufficient follow-up time (31% maturity). At data cutoff, 67 (29%) of 230 patients in the fulvestrant group and 75 (32%) of 232 patients in the anastrozole group had died (HR 0·88, 95% CI 0·63–1·22, p=0·4277).

Treatment effects on progression-free survival were largely consistent across the prespecified patient subgroups (global interaction test p=0·1061), with the following exceptions: patients with previous chemotherapy for locally advanced or metastatic disease, patients with non-measurable disease, patients who were not oestrogen receptor-positive and progesterone receptor-positive at baseline, and patients with visceral disease (figure 3). For patients with non-visceral disease, the HR was 0·59 (95% CI 0·42–0·84), with a median progression-free survival of 22·3 months (95% CI 16·62–32·79) in the fulvestrant group versus 13·8 months (11·04–16·59) in the anastrozole group (figure 3). In the visceral disease subgroup, the HR was 0·99 (0·74–1·33), with median progression-free survival of 13·8 months (11·04–16·53) in the fulvestrant group versus 15·9 months (11·27–16·89) in the anastrozole group. A post-hoc interaction test to assess for consistency of the treatment effects across the visceral and non-visceral subgroups gave a p value of 0·0092.

At data cutoff, median duration of actual exposure to fulvestrant was 14·7 months (range 0·9–37·7) and to anastrozole was 13·9 months (range 0·2–36·0). 166 (73%) of 228 patients in fulvestrant group and 173 (75%) of 232 patients in the anastrozole group reported adverse events (table 3). Serious adverse events were reported by 30 (13%) of 228 patients receiving fulvestrant versus 31 (13%) of 232 patients receiving anastrozole (appendix). Overall, 16 (7%) of 228 patients in the fulvestrant group and 11 (5%) of 232 patients in the anastrozole group discontinued because of adverse events (appendix). Grade 3 or worse adverse events were reported by 51 (22%) of 228 patients receiving fulvestrant and

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