

# Clinical trials of Selective estrogen receptor downregulators (SERDs) for advanced breast cancer (metastatic) in first line endocrine therapy

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## 1 fulvestrant + anastrozole

Trial	Treatments	Patients	Trials design and methods
<b>fulvestrant + anastrozole vs anastrozole</b>			
<b>FACT (Bergh) , 2012</b> [NCT00256698] n=258/256 follow-up:	fulvestrant 500 mg intramuscular on day 1 and 250mg on days 15 and 29 and thereafter every fourth week 3 days, until proven progression or undue toxicity, in combination with anastrozole 1 mg orally per day versus anastrozole orally at 1 mg per day until proven progression or undue toxicity	first-line therapy for patients with receptor-positive postmenopausal breast cancer	open-label Canada
<b>Mehta(SWOG-S0226) , 2012</b> [NCT00075764] n=NA follow-up:	Fulvestrant was administered intramuscularly at a dose of 500 mg on day 1 and 250 mg on days 14 and 28 and monthly thereafter. versus 1 mg of anastrozole orally every day (group 1), with crossover to fulvestrant alone strongly encouraged if the disease progressed,	Postmenopausal women with previously untreated with hormone-receptor (HR)-positive	
<b>CDR0000349337 ongoing</b> [NCT00075764] n=NA follow-up:	anastrozole + fulvestrant intramuscularly on days 1, 14, and 28 during course 1 and then on day 28 of the subsequent courses versus oral anastrozole once daily on days 1-28	first-line therapy in treating postmenopausal women with metastatic breast cancer	open label USA

## References

### FACT (Bergh), 2012:

Bergh J, Jansson PE, Lidbrink EK, Trudeau M, Eiermann W, Brattström D, Lindemann JP, Wiklund F, Henriksson R. FACT: an open-label randomized phase III study of fulvestrant and anastrozole in combination compared with anastrozole alone as first-line therapy for patients with receptor-positive postmenopausal breast cancer. *J Clin Oncol* 2012;30:1919-25 [22370325] [10.1200/JCO.2011.38.1095](https://doi.org/10.1200/JCO.2011.38.1095)

### Mehta(SWOG-S0226), 2012:

Mehta RS, Barlow WE, Albain KS, Vandenberg TA, Dakhil SR, Tirumali NR, Lew DL, Hayes DF, Gralow JR, Livingston RB, Hortobagyi GN. Combination anastrozole and fulvestrant in metastatic breast cancer. *N Engl J Med* 2012;367:435-44 [22853014] [10.1056/NEJMoa1201622](https://doi.org/10.1056/NEJMoa1201622)

### CDR0000349337, 0:

## 2 fulvestrant alone

Trial	Treatments	Patients	Trials design and methods
<b>fulvestrant 250mg vs tamoxifen</b>			
<b>0025 (Howell) , 2004</b> n=313/274 follow-up:	fulvestrant 250 mg, via intramuscular injection, once monthly; versus tamoxifen 20 mg, orally, once daily	advanced breast cancer in postmenopausal women previously untreated with endocrine therapy	double-blind
<b>9238IL/0025</b> <i>unpublished</i> [NCT00241449] n=NA follow-up:	-	first-line treatment for postmenopausal women with advanced breast cancer.	double-blind USA

## References

### 0025 (Howell), 2004:

Howell A, Robertson JF, Abram P, Lichinitser MR, Elledge R, Bajetta E, Watanabe T, Morris C, Webster A, Dimery I, Osborne CK Comparison of fulvestrant versus tamoxifen for the treatment of advanced breast cancer in postmenopausal women previously untreated with endocrine therapy: a multinational, double-blind, randomized trial. *J Clin Oncol* 2004;22:1605-13 [[15117982](#)] [10.1200/JCO.2004.02.112](#)

### 9238IL/0025, 0:

## 3 fulvestrant high dose alone

Trial	Treatments	Patients	Trials design and methods
<b>fulvestrant 500mg vs anastrozole</b>			
<b>FIRST (Robertson) , 2010</b> [NCT00274469] n=NA follow-up:	500 mg intramuscular injection versus anastrozole 1 mg oral tablet	First Line Hormonal Treatment for Postmenopausal Women With Hormone Receptor Positive Advanced Breast Cancer	
<b>FALCON</b> <i>ongoing</i> [NCT01602380] n=NA follow-up:	Fulvestrant 500mg intramuscular injection (2x250mg) versus Anastrozole 1mg tablets	women with locally advanced or metastatic breast cancer who have not had prior hormonal treatment	double-blind USA

## References

### FIRST (Robertson), 2010:

Robertson JFR, Lindemann JPO, Llombart-Cussac A, et al. A comparison of fulvestrant 500 mg with anastrozole as first-line treatment for advanced breast cancer: follow-up analysis from the FIRST study San Antonio Breast Cancer Symposium, San Antonio (TX), December 8-12; 2010 (abstr. S13).

### FALCON, 0:

## 4 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.