

# Clinical trials of Selective estrogen receptor downregulators (SERDs) for advanced breast cancer (metastatic) in all type of patients

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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>GEICAM/2006-10 , 3000</b> <i>unpublished</i> [NCT00543127] n=NA follow-up:	500 mg Im Fulvestrant day 0, 250 mg days 14 and 28 (charge dose); later 250 mg each 28 days during 3 years plus 1 mg oral anastrozole per day during 5 years versus Anastrozole 1 mg daily for 5 years	Postmenopausal women with hormone receptor positive and negative Her2 tumours	open label spain
<b>CDR0000349337</b> <i>ongoing</i> [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
<b>fulvestrant + anastrozole vs exemestane</b>			
<b>SoFEa (Johnston) combination , 2012</b> [NCT00253422] n=NA follow-up:	Fulvestrant With Concomitant Anastrozole versus Exemestane	Postmenopausal Women With ER+ve Locally Advanced/Metastatic Breast Cancer Following Progression on Non-Steroidal Aromatase Inhibitors	

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Trial	Treatments	Patients	Trials design and methods
9238UK/0005 (combination) <i>unpublished</i> [NCT00944918] n=NA follow-up:	-	postmenopausal locally advanced / metastatic breast cancer patients who have progressed on NSAIs	double-blind Korea

## 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 [23370325] [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)

### GEICAM/2006-10, 3000:

### CDR0000349337, 0:

### SoFEa (Johnston) combination, 2012:

Johnston S et al. Fulvestrant alone or with concomitant anastrozole vs exemestane following progression on non-steroidal aromatase inhibitor first results of the SoFEa trial (CRUKE/03/021 & CRUK/09/007) Abstract LBA2, presented at EBCC-8, 2012.

Johnston SR, Kilburn LS, Ellis P, Dodwell D, Cameron D, Hayward L, Im YH, Braybrooke JP, Brunt AM, Cheung KL, Jyothirmayi R, Robinson A, Wardley AM, Wheatley D, Howell A, Coombes G, Sergenson N, Sin HJ, Folkerd E, Dowsett M, Bliss JM Fulvestrant plus anastrozole or placebo versus exemestane alone after progression on non-steroidal aromatase inhibitors in postmenopausal patients with hormone-receptor-positive locally advanced or metastatic breast cancer (SoFEA): a composite, multicentre, phase 3 randomised trial. *Lancet Oncol* 2013;14:989-98 [23902874]

### 9238UK/0005 (combination), 0:

## 2 fulvestrant alone

Trial	Treatments	Patients	Trials design and methods
<b>fulvestrant 250mg vs anastrozole</b>			
0020 (Howell) , 2002 n=NA follow-up:	fulvestrant 250 mg as a once-monthly (one x 5 mL) intramuscular injection versus oral dose of anastrozole 1 mg	-	open-label
Xu et al. , 2011 [NCT00327769] n=121/113 follow-up:	fulvestrant 250 mg/month versus 1 mg/day anastrozole	receptor positive postmenopausal advanced breast cancer.	double-blind china

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
0021 (Osborne) , 2002 [NCT00635713] n=NA follow-up:	intramuscular injection of fulvestrant 250 mg once monthly versus daily oral dose of anastrozole 1 mg	postmenopausal women with advanced breast cancer	double-blind
A011106 <i>ongoing</i> [NCT01953588] n=NA follow-up:	fulvestrant 500 mg IM, Days 1 and 15 of Cycle 1 and Day 1 of Cycles 2-6, every 4 weeks for 6 cycles versus anastrozole 1 mg daily by mouth, Days 1-28, every 4 weeks for 6 cycles	Postmenopausal Patients With Stage II-III Breast Cancer Undergoing Surgery	open label
<b>fulvestrant 250mg vs exemestane</b>			
9238UK/0005 (fulvestrant alone) <i>unpublished</i> [NCT00944918] n=NA follow-up:	fulvestrant Intramuscular injection on days 1, 15, and 29 and then once monthly until disease progression versus exemestane oral, once daily until disease progression.	postmenopausal locally advanced / metastatic breast cancer patients who have progressed on NSAIs	double-blind Korea
SoFEa (Johnston) fulvestrant alone , 2012 [NCT00253422] n=NA follow-up:	fulvestrant intramuscularly (IM) on days 1, 15, and 29 and then once monthly versus exemestane once daily	Postmenopausal Women With ER+ve Locally Advanced/Metastatic Breast Cancer Following Progression on Non-Steroidal Aromatase Inhibitors	Parallel groups UK
<b>fulvestrant 250mg vs exemestane</b>			
EFECT (Chia) <i>unpublished</i> [NCT00065325] n=NA follow-up:	Fulvestrant 500 mg (2 x 5 mL, im injections) administered as a loading dose on Day 0, followed by 250 mg (1 x 5 mL) on Day 14, Day 28 and monthly (ie, 28 3 days) thereafter. versus Exemestane 25 mg administered once daily by mouth (po) from Day 0.	hormone receptor positive postmenopausal women with advanced breast cancer	double-blind
<b>fulvestrant 250mg vs tamoxifen</b>			
0025 (Howell) , 2004 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
9238IL/0025 <i>unpublished</i> [NCT00241449] n=NA follow-up:	-	first-line treatment for postmenopausal women with advanced breast cancer.	double-blind USA

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### 0020 (Howell), 2002:

Howell A, Robertson JF, Quaresma Albano J, Aschermannova A, Mauriac L, Kleeberg UR, Vergote I, Erikstein B, Webster A, Morris C Fulvestrant, formerly ICI 182,780, is as effective as anastrozole in postmenopausal women with advanced breast cancer progressing after prior endocrine treatment. J Clin Oncol 2002;20:3396-403 [[12177099](#)]

### Xu et al., 2011:

Xu B, Jiang Z, Shao Z, Wang J, Feng J, Song S, Chen Z, Gu K, Yu S, Zhang Y, Wang C, Zhang F, Yang J Fulvestrant 250 mg versus anastrozole for Chinese patients with advanced breast cancer: results of a multicentre, double-blind, randomised phase III trial. *Cancer Chemother Pharmacol* 2011;67:223-30 [20938664]

### 0021 (Osborne), 2002:

Osborne CK, Phippen J, Jones SE, Parker LM, Ellis M, Come S, Gertler SZ, May JT, Burton G, Dimery I, Webster A, Morris C, Elledge R, Buzdar A Double-blind, randomized trial comparing the efficacy and tolerability of fulvestrant versus anastrozole in postmenopausal women with advanced breast cancer progressing on prior endocrine therapy: results of a North American trial. *J Clin Oncol* 2002;20:3386-95 [12177098]

### A011106, 0:

Ellis MJ, Suman VJ, Hoog J, Goncalves R, Sanati S, Creighton CJ, DeSchryver K, Crouch E, Brink A, Watson M, Luo J, Tao Y, Barnes M, Dowsett M, Budd GT Ki67 Proliferation Index as a Tool for Chemotherapy Decisions During and After Neoadjuvant Aromatase Inhibitor Treatment of Breast Cancer: Results From the American College of Surgeons Oncology Group Z1031 Trial (Alliance). *J Clin Oncol* 2017;:JCO2016694406 [28045625]

### 9238UK/0005 (fulvestrant alone), 0:

### SoFEa (Johnston) fulvestrant alone, 2012:

Johnston S et al. Fulvestrant alone or with concomitant anastrozole vs exemestane following progression on non-steroidal aromatase inhibitor first results of the SoFEa trial (CRUKE/03/021 & CRUK/09/007) Abstract LBA2, presented at EBCC-8, 2012.

Johnston SR, Kilburn LS, Ellis P, Dodwell D, Cameron D, Hayward L, Im YH, Braybrooke JP, Brunt AM, Cheung KL, Jyothirmayi R, Robinson A, Wardley AM, Wheatley D, Howell A, Coombes G, Sergenson N, Sin HJ, Folkler E, Dowsett M, Bliss JM Fulvestrant plus anastrozole or placebo versus exemestane alone after progression on non-steroidal aromatase inhibitors in postmenopausal patients with hormone-receptor-positive locally advanced or metastatic breast cancer (SoFEA): a composite, multicentre, phase 3 randomised trial. *Lancet Oncol* 2013;14:989-98 [23902874]

### EFFECT (Chia), 0:

### 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 ongoing</b> [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
<b>fulvestrant 500mg vs control</b>			

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Trial	Treatments	Patients	Trials design and methods
<b>FUMANCE</b> <i>ongoing</i> [NCT02383030] n=NA follow-up:	-	After First-line Chemotherapy in HER2 - Postmenopausal MBC Patients	open label italy
<b>fulvestrant 500mg vs fulvestrant 250mg</b>			
<b>FINDER 1 (Ohno) , 2010</b> n=NA follow-up:	-	postmenopausal Japanese women with advanced breast cancer	
<b>FINDER 2 , 2010</b> [NCT00313170] n=NA follow-up:	500 mg (high dose [HD]; 500 mg/month plus 500 mg on day 14 of Month 1). versus fulvestrant: 250 mg/month (approved dose [AD]);	Western postmenopausal women recurring or progressing after prior endocrine therapy	
<b>D6997L00021 , 3000</b> <i>unpublished</i> [NCT01300351] n=NA follow-up:	Fulvestrant 500mg (2 syringes of Fulvestrant 250mg), Fulvestrant 500 mg i.m. every 28 (+/- 3) days plus an additional 500 mg on day 14 (+/-3) of first month only versus Fulvestrant 250mg (1 syringe of fulvestrant 250mg + 1 syringe matching placebo), Fulvestrant 250 mg and matching placebo i.m. every 28 (+/- 3) days plus an additional 2 placebo syringes on day 14 (+/-3) of first month only	Chinese postmenopausal women with oestrogen receptor positive advanced breast cancer who have failed a prior endocrine treatment	double-blind China
<b>CONFIRM (Di Leo) , 2010</b> [NCT00099437] n=NA follow-up:	fulvestrant 500 mg (500 mg intramuscularly [IM] on day 0, then 500 mg IM on days 14 and 28 and every 28 days thereafter) versus fulvestrant 250 mg every 28 days	women with oestrogen receptor positive advanced breast cancer who have failed on a previous endocrine treatment	double-blind US

## 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 812; 2010 (abstr. S13).

### FALCON, 0:

### FUMANCE, 0:

### FINDER 1 (Ohno), 2010:

Ohno S, Rai Y, Iwata H, Yamamoto N, Yoshida M, Iwase H, Masuda N, Nakamura S, Taniguchi H, Kamigaki S, Noguchi S Three dose regimens of fulvestrant in postmenopausal Japanese women with advanced breast cancer: results from a double-blind, phase II comparative study (FINDER1). *Ann Oncol* 2010;21:2342-7 [20494961] [10.1093/annonc/mdq249](https://doi.org/10.1093/annonc/mdq249)

### FINDER 2, 2010:

Pritchard KI, Rolski J, Papai Z, Mauriac L, Cardoso F, Chang J, Panasci L, Ianuli C, Kahan Z, Fukase K, Lindemann JP, Macpherson MP, Neven P Results of a phase II study comparing three dosing regimens of fulvestrant in postmenopausal women with advanced breast cancer (FINDER2). *Breast Cancer Res Treat* 2010 Sep;123:453-61 [20632084] [10.1007/s10549-010-1022-9](https://doi.org/10.1007/s10549-010-1022-9)

### D6997L00021, 3000:

#### **CONFIRM (Di Leo), 2010:**

Di Leo A, Jerusalem G, Petruzella L, Torres R, Bondarenko IN, Khasanov R, Verhoeven D, Pedrini JL, Smirnova I, Lichinitser MR, Pendergrass K, Garnett S, Lindemann JP, Sapunar F, Martin M Results of the CONFIRM phase III trial comparing fulvestrant 250 mg with fulvestrant 500 mg in postmenopausal women with estrogen receptor-positive advanced breast cancer. *J Clin Oncol* 2010;28:4594-600 [[20855825](#)] [10.1200/JCO.2010.28.8415](#)

## **4 About TrialResults-center.org**

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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.

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