

Clinical trials of nontaxane microtubule dynamics inhibitor for advanced breast cancer (metastatic) in all type of patients

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1 nontaxane microtubule dynamics inhibitor

Trial	Treatments	Patients	Trials design and methods
eribulin vs capecitabine			
Trial 301 (Kaufman) , 2015 [NCT00337103] n=554/548 follow-up:	eribulin mesylate 1.4 mg/m ² (equivalent to eribulin 1.23 mg/m ² [expressed as free base]) intravenously over 2 to 5 minutes on days 1 and 8 until disease progression, unacceptable toxicity, or patient/investigator request to discontinue versus capecitabine 1.25 g/m ² orally twice per day on days 1 to 14, both in 21-day cycles	patients with locally advanced or metastatic breast cancer previously treated with an anthracycline and a taxane	open-label
eribulin+cyclophosphamide vs docetaxel+cyclophosphamide			
SCRI BRE 197 <i>ongoing</i> [NCT01527487] n=NA follow-up:	Eribulin: 1.4mg/m ² IV (Days 1 and 8) given short (1.5 minutes) IV infusion, per institutional standard Cyclophosphamide: 600 mg/m ² IV (Day 1), given by IV infusion, per institutional standard versus Docetaxel: 75 mg/m ² IV (Day 1), given by 1-hour IV infusion Cyclophosphamide: 600 mg/m ² IV (Day 1), given by IV infusion, per institutional standard	neoadjuvant therapy for locally advanced HER2-negative breast cancer	
eribulin vs ixabepilone			
Vahdat , 2013 [NCT00879086] n=52/52 follow-up:	eribulin mesylate (1.4 mg/m ² , 25 min intravenous on days 1 and 8) versus ixabepilone (40 mg/m ² , 3 h intravenous on day 1) on a 21-day cycle	patients with metastatic breast cancer	Parallel groups open-label
eribulin vs paclitaxel			
NCT02037529 <i>ongoing</i> [NCT02037529] n=910 follow-up:	Eribulin on Days 1 and 8 of each cycle (cycle length: 21 days) versus Paclitaxel on Days 1, 8, and 15 of each cycle (cycle length: 28 days)	first and second-line HER2 negative patients with locally recurrent or metastatic breast cancer	Parallel groups open-label
eribulin+gemcitabine vs paclitaxel+gemcitabine			

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Trial	Treatments	Patients	Trials design and methods
2014-0857 <i>ongoing</i> [NCT02263495] n=NA follow-up:	Eribulin 1.0 mg/m ² , 2-5min iv ,Day1& Day8 every 3weeks + Gemcitabine 1,000 mg/m ² ,Day1& Day8 every 3weeks versus Paclitaxel 175mg/m ² IV , Day1,every 3weeks + Gemcitabine 1250mg/m ² IV ,Day1& Day8 every 3weeks	Patients with HER-2 negative MBC as first-line chemotherapy	Parallel groups open-label Korea
eribulin vs treatment of physician			
EMBRACE (Cortes) , 2011 [NCT00388726] n=508/254 follow-up:	eribulin mesilate (14 mg/m administered intravenously during 25 min on days 1 and 8 of a 21-day cycle) versus treatment of physicians choice	patients with metastatic breast cancer who had received between two and five previous chemotherapy regimens (two or more for advanced disease), including an anthracycline and a taxane, unless contraindicated.	open-label 19 countries
eribulin vs vinorelbine			
E7389-C086-304 <i>ongoing</i> [NCT02225470] n=NA follow-up:	eribulin mesylate 1.4 mg/m ² administered as an intravenous bolus over 2 to 5 minutes on Days 1 and 8 of each 21-day cycle. versus vinorelbine at 25 mg/m ² administered as an intravenous bolus on Days 1, 8, and 15 of each 21-day treatment cycle.	Female Subjects With Locally Recurrent or Metastatic Breast Cancer, Previously Treated With At Least Two and a Maximum of Five Prior Chemotherapy Regimens, Including an Anthracycline and a Taxane	Parallel groups open-label China

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References

Trial 301 (Kaufman), 2015:

Kaufman PA, Awada A, Twelves C, Yelle L, Perez EA, Velikova G, Olivo MS, He Y, Dutcus CE, Cortes J, Phase III open-label randomized study of eribulin mesylate versus capecitabine in patients with locally advanced or metastatic breast cancer previously treated with an anthracycline and a taxane. *J Clin Oncol* 2015;33:594-601. [[25605862](#)] [10.1200/JCO.2013.52.4892](#)

Twelves C, Cortes J, Vahdat LT, Wanders J, Akerele C, Kaufman PA Phase III trials of eribulin mesylate (E7389) in extensively pretreated patients with locally recurrent or metastatic breast cancer. *Clin Breast Cancer* 2010;10:160-3 [[20299316](#)]

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Vahdat, 2013:

Vahdat LT, Garcia AA, Vogel C, Pellegrino C, Lindquist DL, Iannotti N, Gopalakrishna P, Sparano JA, Eribulin mesylate versus ixabepilone in patients with metastatic breast cancer: a randomized Phase II study comparing the incidence of peripheral neuropathy. *Breast Cancer Res Treat* 2013;140:341-51. [[23877339](#)] [10.1007/s10549-013-2574-2](#)

NCT02037529, :

2014-0857, 0:

EMBRACE (Cortes), 2011:

Cortes J, O'Shaughnessy J, Loesch D, Blum JL, Vahdat LT, Petrakova K, Chollet P, Manikas A, Diras V, Delozier T, Vladimirov V, Cardoso F, Koh H, Bougnoux P, Dutcus CE, Seegobin S, Mir D, Meneses N, Wanders J, Twelves C, , Eribulin monotherapy versus treatment of physician's choice in patients with metastatic breast cancer (EMBRACE): a phase 3 open-label randomised study. *Lancet* 2011;377:914-23. [[21376385](#)] [10.1016/S0140-6736\(11\)60070-6](#)

Twelves C, Cortes J, Vahdat LT, Wanders J, Akerele C, Kaufman PA Phase III trials of eribulin mesylate (E7389) in extensively pretreated patients with locally recurrent or metastatic breast cancer. *Clin Breast Cancer* 2010;10:160-3 [[20299316](#)]

E7389-C086-304, 0:

2 About TrialResults-center.org

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