

Clinical trials of direct factor Xa inhibitors for atrial fibrillation in all type of patients

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1 oral factor Xa inhibitors

Trial	Treatments	Patients	Trials design and methods
edoxaban low dose vs warfarin standard dose			
ENGAGE-AF TIMI 48 Low dose , 2013 [NCT00781391] n=7034/7036 follow-up: 2.8 years	edoxaban xxx once daily versus warfarin (INR 2-3)	AF patients (CHADS2 >=2)	double blind 46 countries
apixaban vs aspirin			
AVERROES , 2011 [NCT00496769] n=2808/2791 follow-up: maximum 21 months	apixaban 5 mg (or 2.5 mg) twice daily versus aspirin 81-324 md daily	patients with atrial fibrillation who have failed or are unsuitable for vitamin K antagonist treatment	Parallel groups double blind 36 countries
apixaban vs warfarin standard dose			
ARISTOTLE , 2011 [NCT00412984] n=9120/9081 follow-up: 1.8 yrs (median)	apixaban 5mg twice daily versus warfarin adjusted for an INR between 2 and 3	subjects with atrial fibrillation and risk factors for stroke	Parallel groups double blind 39 countries
phase 2 apixaban unpublished [NCT00787150] n=222 follow-up: 12 weeks	apixaban 5 or 2.5 mg twice daily versus warfarin	patient with non valvular AF	Parallel groups double blind
edoxaban vs warfarin standard dose			
Weitz (edoxaban phase 2) unpublished [NCT00504556] n=1146 follow-up: 3 months	Four Fixed Dose Regimens of edoxaban (DU-176b) versus warfarin	Subjects With Non- Valvular Atrial Fibrillation	Parallel groups double-blind USA, Europe, South and central america,
phase 2 edoxaban unpublished [NCT00806624] n=NA follow-up:	edoxaban (DU-176b) versus warfarin	male and female subjects aged 18 to 80 years, inclusive, with non-valvular AF and a CHADS2 Score of at least 1	Parallel groups double-blind China
edoxaban high dose vs warfarin standard dose			

continued...

Trial	Treatments	Patients	Trials design and methods
ENGAGE-AF TIMI 48 High dose , 2013 [NCT00781391] n=7035/7036 follow-up: 2.8 years	edoxaban 60mg once daily versus warfarin (INR 2-3)	AF patients (CHADS2 >=2)	Parallel groups double blind 46 countries
rivaroxaban vs warfarin standard dose			
ROCKET-AF , 2010 [NCT00403767] n=7131/7133 follow-up: median 1.94 y	Rivaroxaban 20mg p.o. once daily versus Warfarin p.o. once daily titrated to a target INR of 2.5 (range 2.0 to 3.0, inclusive)	Subjects With Non-Valvular Atrial Fibrillation	Parallel groups double blind 45 countries
ROCKET J ongoing [NCT00494871] n=NA follow-up:	Rivaroxaban versus warfarin	-	parallel groups double-blind Japan
YM150 vs warfarin standard dose			
phase 2 YM150 unpublished [NCT00448214] n=NA follow-up:	YM150 ASTELLAS versus warfarin	subjects with non-valvular atrial fibrillation	Parallel groups open Australia
OPAL-2 ongoing [NCT00938730] n=NA follow-up:	YM150 versus warfarin	subjects with non-valvular atrial fibrillation	double-blind Australia

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Aug 27;: [21870978] [10.1056/NEJMoa1107039](https://doi.org/10.1056/NEJMoa1107039)

phase 2 apixaban, 0:

Weitz (edoxaban phase 2), 0:

phase 2 edoxaban, 0:

ENGAGE-AF TIMI 48 High dose, 2013:

Ruff CT, Giugliano RP, Antman EM, Crugnale SE, Bocanegra T, Mercuri M, Hanyok J, Patel I, Shi M, Salazar D, McCabe CH, Braunwald E Evaluation of the novel factor Xa inhibitor edoxaban compared with warfarin in patients with atrial fibrillation: design and rationale for the Effective aNticoagulation with factor xA next GEneration in Atrial Fibrillation-Thrombolysis In Myocardial Infarction study 48 (ENGAGE AF-TIMI 48). *Am Heart J* 2010;160:635-41 [20934556] [10.1016/j.ahj.2010.06.042](https://doi.org/10.1016/j.ahj.2010.06.042)

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ROCKET J, :

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OPAL-2, :

2 About TrialResults-center.org

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