

Clinical trials of edoxaban

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1 atrial fibrillation

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
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Weitz (edoxaban phase 2) unpublished [NCT00504556] n=1146 follow-up: 3 months	Four Fixed Dose Regimens of edoxaban (DU-176b) versus warfarin	Subjects With Non- Valvular Atrial Fibrillation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phase 2 edoxaban unpublished [NCT00806624] n=NA follow-up:	edoxaban (DU-176b) versus warfarin	male and female subjects aged 18 to 80 years, inclusive, with non-valvular AF and a CHADS2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			
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

More details and results :

- antithrombotics for atrial fibrillation in primary prevention of thromboembolic events at <http://www.trialresultscenter.org/go-Q57>
- direct factor Xa inhibitors for atrial fibrillation in all type of patients at <http://www.trialresultscenter.org/go-Q373>
- direct oral anticoagulant (DAO) for atrial fibrillation in all type of patients at <http://www.trialresultscenter.org/go-Q391>

References

ENGAGE-AF TIMI 48 Low dose, 2013:

Giugliano RP, Ruff CT, Braunwald E, Murphy SA, Wiviott SD, Halperin JL, Waldo AL, Ezekowitz MD, Weitz JI, Pinar J, Ruzyllo W, Ruda M, Koretsune Y, Betcher J, Shi M, Grip LT, Patel SP, Patel I, Hanyok JJ, Mercuri M, Antman EM. Edoxaban versus warfarin in patients with atrial fibrillation. *N Engl J Med* 2013 Nov 28;369:2093-104 [[24251359](#)]

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](#)

Weitz (edoxaban phase 2), 0:

unpublished

phase 2 edoxaban, 0:

unpublished

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](#)

Giugliano RP, Ruff CT, Braunwald E, Murphy SA, Wiviott SD, Halperin JL, Waldo AL, Ezekowitz MD, Weitz JI, Pinar J, Ruzyllo W, Ruda M, Koretsune Y, Betcher J, Shi M, Grip LT, Patel SP, Patel I, Hanyok JJ, Mercuri M, Antman EM. Edoxaban versus warfarin in patients with atrial fibrillation. *N Engl J Med* 2013 Nov 28;369:2093-104 [[24251359](#)]

2 thrombosis prevention

Trial	Treatments	Patients	Trials design and methods
edoxaban vs placebo			
DU176b-04 <i>ongoing</i> [NCT01203072] n=NA follow-up:	edoxaban 5, 15, 30, 60 mg once daily for 2 weeks versus placebo	elective total knee arthroplasty	parallel groups double-blind Japan
edoxaban vs enoxaparin (short duration)			
STARS J-V [NCT01181167] n=255/248 follow-up:	edoxaban 30 mg once daily for 11 to 14 days versus subcutaneous enoxaparin 2,000 IU, equivalent to 20 mg, twice daily (BID) for 11 to 14 days	total hip arthroplasty	Parallel groups double-blind japan

continued...

Trial	Treatments	Patients	Trials design and methods
edoxaban vs enoxaparin			
DU176b-B-J302 <i>ongoing</i> [NCT01181102] n=NA follow-up:	edoxaban 30mg once daily versus enoxaparin sodium (enoxaparin sodium 20mg(=2000IU)/0.2ml twice daily, subcutaneous injection)	elective total knee arthroplasty	parallel groups double-blind Japan
DU176b-B-J303 <i>ongoing</i> [NCT01181141] n=NA follow-up:	edoxaban 30mg once daily versus Enoxaparin sodium 20mg(=2000IU)/0.2ml twice daily, subcutaneous injection	elective hip fracture surgery	open Japan
DU176b-B-J304 <i>ongoing</i> [NCT01181167] n=NA follow-up:	edoxaban 30mg once daily versus (enoxaparin sodium 20mg(=2000IU)/0.2ml twice daily, subcutaneous injection)	elective total hip arthroplasty	parallel groups double-blind Japan

More details and results :

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- antithrombotics for thrombosis prevention in orthopedic surgery at <http://www.trialresultscenter.org/go-Q37>
- antithrombotics for thrombosis prevention in elective hip replacement at <http://www.trialresultscenter.org/go-Q39>
- anticoagulant for thrombosis prevention in orthopedic surgery at <http://www.trialresultscenter.org/go-Q184>
- direct factor Xa inhibitors for thrombosis prevention in all type of patients at <http://www.trialresultscenter.org/go-Q371>
- direct oral anticoagulant (DAO) for thrombosis prevention in all type of patients at <http://www.trialresultscenter.org/go-Q393>
- direct oral anticoagulant (DAO) for thrombosis prevention in elective hip replacement at <http://www.trialresultscenter.org/go-Q395>
- direct oral anticoagulant (DAO) for thrombosis prevention in orthopaedic surgery at <http://www.trialresultscenter.org/go-Q475>

References

DU176b-04, 0:

ongoing trial NCT01203072

STARS J-V, 0:

DU176b-B-J302, 0:

ongoing trial NCT01181102

DU176b-B-J303, 0:

ongoing trial NCT01181141

DU176b-B-J304, 0:

ongoing trial NCT01181167

3 venous thrombosis

Trial	Treatments	Patients	Trials design and methods
edoxaban vs dalteparin			
Hokusai-VTE Cancer , 2017 [NCT02073682] n=522/524 follow-up:	low-molecular-weight heparin for at least 5 days followed by oral edoxaban at a dose of 60 mg once daily. Treatment was given for atleast 6 months and up to 12 months. versus subcutaneous dalteparin at a dose of 200 IU per kilogram of body weight once daily for 1 month followed by dalteparin at a dose of 150 IU per kilogram once daily	patients with cancer who had acute symptomatic or incidental venous thromboembolism	open label
heparin/edoxaban vs heparin/VKA			
Edoxaban Hokusai VTE , 2013 [NCT00986154] n=4143/4149 follow-up:	heparin then edoxaban 60mg daily (30mg if creatine clearnce of 30 to 50 ml/min or <60kg) for 3 to 12 months versus heparin then warfarin	patients with acute venous thromboembolism, who had initially received heparin,	Parallel groups double-blind

More details and results :

- antithrombotics for venous thrombosis in patients with cancer at <http://www.trialresultscenter.org/go-Q103>
- direct oral anticoagulant (DAO) for venous thrombosis in all types of patients at <http://www.trialresultscenter.org/go-Q505>
- direct oral anticoagulant (DAO) for venous thrombosis in patients with cancer at <http://www.trialresultscenter.org/go-Q737>

References

Hokusai-VTE Cancer, 2017:

Raskob GE Edoxaban for the Treatment of Cancer-Associated Venous Thromboembolism. N Engl J Med 2018;378:615-624 [29231094] [10.1056/NEJMoa1711948](https://doi.org/10.1056/NEJMoa1711948)

Edoxaban Hokusai VTE, 2013:

Edoxaban versus Warfarin for the Treatment of Symptomatic Venous Thromboembolism. N Engl J Med 2013 Aug 31;: [23991658] [10.1056/NEJMoa1306638](https://doi.org/10.1056/NEJMoa1306638)