Clinical trials of direct oral anticoagulant (DAO) for atrial fibrillation in all type of patients

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1 oral direct thrombin inhibitor

Trial	Treatments	Patients	Trials design and methods
AZD0837 vs aspirin			
phase 2 AZD0837 *unpublished* [NCT00623779] n=NA follow-up:	AZD0837 versus aspirin	patients with atrial fibrillation, who are appropriate for but unable or unwilling to take Vitamin-K antagonist(VKA) therapy	Parallel groups open
AZD0837 vs warfarin standard dose			
Lip (phase 2 AZD0837) , 2009 *unpublished* [NCT00684307] n=636/318 follow-up: 3 or 9 months	AZD0837 for 3-9 months versus dose-adjusted Vitamin-K antagonists (VKA) (aiming for an international normalized ratio (INR) 2.0 to 3.0)	patients with non-valvular atrial fibrillation (AF) with one or more additional risk factors for stroke	Parallel groups double blind
dabigatran vs warfarin standard dose			
phase 2 dabigatran *unpublished* [NCT01136408] n=NA follow-up:	Dabigatran 110, 220, 300 mg twice daily versus warfarin	patients with non-valvular atrial fibrillation (paroxysmal, persistent or permanent)	Parallel groups open Japan
dabigatran 110mg vs warfarin standard dose			
RE-LY (110mg) , 2009 [NCT00262600] n=6015/6022 follow-up: 2 y (median)	dabigatran 110 mg twice a day versus warfarin adjusted dose to a 2-3 INR	Patients With Non-Valvular Atrial Fibrillation	Parallel groups open (blind assessment) 44 countries
dabigatran 150mg vs warfarin standard dose			
PETRO (150mg) , 2007 n=166/70 follow-up: 12 weeks	dabigatran 150 mg twice daily (alone or combined with 81- or 325-mg aspirin) versus warfarin administered to achieve an international normalized ratio of 2 to 3 for	patients with AF at high risk for thromboembolic events	Factorial plan double blind Denmark, The netehrlands, Sweden, US
RE-LY (150mg) , 2009 [NCT00262600] n=6076/6022 follow-up: 2 y (median)	dabigatran 150 mg twice a day versus warfarin adjusted-dose to a 2.0 to 3.0 INR	Patients With Non-Valvular Atrial Fibrillation	Parallel groups open (blind assessment) 44 countries
ximelagatran vs warfarin standard dose			

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Trial	Treatments	Patients	Trials design and methods
SPORTIF V , 2005 n=1960/1962 follow-up: 20 months	ximelegatran 36 mg twice daily versus warfarin standard dose(target INR 2-3)	One or more stroke risk factor in addition to atrial fibrillation.High risk patients with non valvular atrial fibrillation.	Parallel groups Double blind north america
SPORTIF II (ximelagatran vs warfarin standard dose) , 2002 n=187/67 follow-up: 16 weeks	ximelegatran 20,40,60 mg twice daily versus warfarin standard dose(target INR 2-3)	Medium to high risk patients with chronic non valvular atrial fibrillation.	Parallel groups Open Europe ,USA
SPORTIF III , 2003 n=1704/1703 follow-up: 17.4 months	ximelagatran 36 mg twice daily versus warfarin standard dose (target INR 2-3)	One or more stroke risk factor in addition to AF.High risk patients with non valvular atrial fibrillation.	Parallel groups Open europe,asia,australasia

References

phase 2 AZD0837, 0:

Lip (phase 2 AZD0837), 2009:

Lip GY, Rasmussen LH, Olsson SB, Jensen EC, Persson AL, Eriksson U, Whlander KF Oral direct thrombin inhibitor AZD0837 for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation: a randomized dose-guiding, safety, and tolerability study of four doses of AZD0837 vs. vitamin K antagonists. Eur Heart J 2009;30:2897-907 [19690349] 10.1093/eurheartj/ehp318

phase 2 dabigatran, 0:

RE-LY (110mg), 2009:

PETRO (150mg), 2007:

RE-LY (150mg), 2009:

SPORTIF V, 2005:

SPORTIF II (ximelagatran vs warfarin standard dose), 2002:

SPORTIF III, 2003:

2 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 warfarin standard dose			

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Trial	Treatments	Patients	Trials design and methods
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			
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

References

ENGAGE-AF TIMI 48 Low dose, 2013:

ARISTOTLE, 2011:
phase 2 apixaban, 0:
Weitz (edoxaban phase 2), 0:
phase 2 edoxaban, 0:
ENGAGE-AF TIMI 48 High dose, 2013:
ROCKET-AF, 2010:
ROCKET J, :
phase 2 YM150, 0:
OPAL-2, :

3 synthetic oligosaccharide

Trial	Treatments	Patients	Trials design and methods
idraparinux vs warfarin standard dose			
AMADEUS , 2008 [NCT00070655] n=2283/2293 follow-up: 10.7 months	subcutaneous idraparinux 25 mg weekly versus adjusted-dose vitamin K antagonists (target of an international normalised ratio of 23)	patients with atrial fi brillation at risk for thromboembolism	Parallel groups open
idraparinux BOREALIS-AF *ongoing* [NCT00580216] n=NA follow-up:	idraparinuxonce-weekly subcutaneous injection versus warfarin oral INR adjusted-dose	-	Parallel groups double blind

References

AMADEUS, 2008:
idraparinux BOREALIS-AF, 0:

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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