

	RE-LY	ROCKET-AF	ARISTOTLE	AVERROES	BOREALIS-AF
Study drug	dabigatran etexilate	rivaroxaban	apixaban	apixaban	biotinylated idraparinux
Mechanism of action	direct thrombin inhibitor	direct factor Xa inhibitor	direct factor Xa inhibitor	direct factor Xa inhibitor	indirect factor Xa inhibitor
Route of administration	oral	oral	oral	oral	parenteral (s.c.)
Terminal half-life	17 h	9-12 h	8-15 h	8-15 h	130 h
Excretion	80% renal; 20% hepatic	60% renal - 28% liver and faecal	25% renal, 75% non-renal	25% renal, 75% non-renal	mainly renal
Dose	dabigatran etex. 110 mg b.i.d. vs. dabigatran etex. 150 mg b.i.d.	20 mg o.d. 15 mg o.d. for CrCl 30-49	5 mg b.i.d. 2.5 o.d. for risk categories	5 mg b.i.d. 2.5 o.d. for risk categories	3 mg weekly for 7 weeks followed by 2 mg weekly or 1.5 mg weekly for risk categories
Comparator	warfarin	warfarin	warfarin	aspirin 81 to 325 mg QD	warfarin
Design	Prospective Randomized Open-label with Blinded Adjudication of Events - PROBE	double-blind, double-dummy	double-blind, double-dummy	double blind	double-blind, double-dummy
Primary Outcome	stroke or non-CNS systemic embolism	stroke or non-CNS systemic embolism	stroke or non-CNS systemic embolism	stroke or non-CNS systemic embolism	stroke or non-CNS systemic embolism
	event-driven (>450 events), non-inferiority	event-driven (>400 events), non-inferiority	event-driven (>300 events), non-inferiority	event-driven (>226 events), superiority	event-driven (>278 events), non-inferiority

N. of patients	approx. 15,000	approx 14,000	approx 15,000	approx 5,600	approx 9,600
Non-inferiority margin	01:46	1.46	01:44		01:38
Inclusion	non-valvular AF, moderate-high-risk (CHADS \geq 1)	non-valvular AF, moderate-high-risk (CHADS \geq 2) recruitment emphasis on warfarin-naïve patients	AF, moderate-high-risk (CHADS \geq 1) recruitment emphasis on warfarin-naïve patients	AF, moderate-high-risk (CHADS \geq 1)	AF, moderate-high-risk (CHADS \geq 1)
Exclusion	CrCl <30mL/min and significant liver disease	CrCl <30mL/min, significant liver disease, ketoconazole, protease inhibitors	CrCl <25 mL/min and significant liver disease	CrCl <25 mL/min and significant liver disease	CrCl <30 mL/min
Participating centers	>800	1100	800	600	800
Follow-up duration	3 years	3 years	3 years	3 years	9 months following randomization of the last patient
Expected publication	2008	2010	2010	2012	2012
Sponsor	Boehringer-Ingelheim	Bayer - Johnson & Johnson	Bristol Myers-Squibb	Bristol Myers-Squibb	Sanofi-Aventis