

# Clinical trials of direct factor Xa inhibitors for acute coronary syndrome in all type of patients

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## 1 oral direct thrombin inhibitor

Trial	Treatments	Patients	Trials design and methods
<b>dabigatran vs placebo</b>			
<b>REDEEM , 2009</b> <i>unpublished</i> [NCT00621855] n=1501/373 follow-up: 6 months	dabigatran 4 dosages (50mg twice daily, 75mg twice daily, 110mg twice daily, 150mg twice daily) versus placebo	patients with recent acute coronary syndromes (ST- or non-ST-elevation myocardial infarction)	Parallel groups double blind

## References

### REDEEM, 2009:

Oldgren J, Budaj A, Granger CB, Khder Y, Roberts J, Siegbahn A, Tijssen JG, Van de Werf F, Wallentin L Dabigatran vs. placebo in patients with acute coronary syndromes on dual antiplatelet therapy: a randomized, double-blind, phase II trial. *Eur Heart J* 2011 Nov;32:2781-9 [21551462]

## 2 oral factor Xa inhibitor

Trial	Treatments	Patients	Trials design and methods
<b>apixaban vs placebo</b>			
<b>APPRAISE 2 , 2011</b> [NCT00831441] n=3705/3687 follow-up: 8 months	apixaban 5mg twice daily versus placebo	patients with a recent acute coronary syndrome and at least two additional risk factors for recurrent ischemic events	Parallel groups double blind 39 countries
<b>APPRAISE-1 (10mg od) , 2009</b> [NCT00313300] n=318/611 follow-up: 6 months	apixaban 10 mg once daily versus placebo	patients with a recent ST-elevation or nonST-elevation acute coronary syndrome(<7 days)	Parallel groups double blind Europe, Middle East, North America
<b>APPRAISE-1 (2.5 mg bid) , 2009</b> [NCT00313300 ] n=NA follow-up: 6 months	Apixaban 2.5mg twice daily versus placebo	patients with a recent ST-elevation or nonST-elevation acute coronary syndrome(<7 days)	double blind Europe, Middle East, North America

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>APPRAISE japan</b> <i>ongoing</i> [NCT00852397] n=NA follow-up:	2 doses of apixaban (2.5 mg BID and 5.0 mg BID) for 24 weeks in combination with standard therapy (aspirin and /or additional antiplatelet therapy) versus placebo	patients with recent (<=7 days) acute coronary syndrome	double-blind Japan
<b>rivaroxaban 2.5mg vs placebo</b>			
<b>ATLAS ACS-TIMI 46 (2.5mg)</b> , 2009 [NCT00402597] n=152/1160 follow-up: 6 months	rivaroxaban 2.5 mg twice daily versus placebo	recent ACS patients treated with aspirin alone (n=761) or aspirin plus clopidogrel (n=2730)	double blind 27 countries
<b>ATLAS ACS 2 - TIMI 51 (2.5mg)</b> , 2011 [NCT00809965] n=5174/5176 follow-up: 13 months	rivaroxaban 2.5 mg twice daily in addition to standard care versus placebo	patients with a recent ACS	Parallel groups double blind 44 countries
<b>rivaroxaban 5mg vs placebo</b>			
<b>ATLAS ACS-TIMI 46 (5mg)</b> , 2009 [NCT00402597] n=519/1160 follow-up: 6 months	rivaroxaban 5 mg twice daily versus placebo	recent ACS patients treated with aspirin alone (n=761) or aspirin plus clopidogrel (n=2730)	Parallel groups double blind 27 countries
<b>ATLAS ACS 2 - TIMI 51 (5mg)</b> , 2011 [NCT00809965] n=5176/5176 follow-up: 13 months	rivaroxaban 5 mg twice daily in addition to standard care versus placebo	patients with a recent ACS	double blind 44 countries
<b>ximelagatran vs placebo</b>			
<b>ESTEEM</b> , 2003 n=1245/638 follow-up: 6 months	oral ximelagatran at doses of 24 mg, 36 mg, 48 mg, or 60 mg twice daily versus placebo	patients who had had recent ST-elevation or non-STelevation myocardial infarction	Parallel groups double-blind
<b>otamixaban vs unfractionated heparin</b>			
<b>SEPIA-ACS1 TIMI 42</b> , 2009 [NCT00317395] n=2792/449 follow-up: 7 days	otamixaban 5 doses (008 mg/kg bolus followed by 0.035, 0.070, 0.105, 0.140, 0.175 mg/kg/h) versus Heparin+eptifibatide	patients with non-ST-elevation acute coronary syndromes	Parallel groups double blind 36 countries

## References

### APPRAISE 2, 2011:

Alexander JH, Lopes RD, James S, Kilaru R, He Y, Mohan P, Bhatt DL, Goodman S, Verheugt FW, Flather M, Huber K, Liaw D, Husted SE, Lopez-Sendon J, De Caterina R, Jansky P, Darius H, Vinereanu D, Cornel JH, Cools F, Atar D, Leiva-Pons JL, Keltai M, Ogawa H Apixaban with Antiplatelet Therapy after Acute Coronary Syndrome. *N Engl J Med* 2011 Jul 24; [21780946] [10.1056/NEJMoa1105819](https://doi.org/10.1056/NEJMoa1105819)

**APPRAISE-1 (10mg od), 2009:**

Apixaban, an Oral, Direct, Selective Factor Xa Inhibitor, in Combination With Antiplatelet Therapy After Acute Coronary Syndrome. Results of the Apixaban for Prevention of Acute Ischemic and Safety Events (APPRAISE) Trial. Circulation 2009;: [19470889]

**APPRAISE-1 (2.5 mg bid), 2009:**

**APPRAISE japan, :**

**ATLAS ACS-TIMI 46 (2.5mg), 2009:**

**ATLAS ACS 2 - TIMI 51 (2.5mg), 2011:**

**ATLAS ACS-TIMI 46 (5mg), 2009:**

**ATLAS ACS 2 - TIMI 51 (5mg), 2011:**

**ESTEEM, 2003:**

**SEPIA-ACS1 TIMI 42, 2009:**

### 3 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.

TrialResults-center is non-profit and self-funded.