# 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 |
|---|---|---|---|
| **dabigatran vs placebo** | | | |
| REDEEM , 2009 *unpublished*<br>[NCT00621855]<br>n=1501/373<br>follow-up: 6 months | dabigatran 4 dosages (50mg twice daily, 75mg twice daily, 110mg twice daily, 150mg twice daily)<br>versus<br>placebo | patients with recent acute coronary syndromes (ST- or non-ST-elevation myocardical infarction) | Parallel groups<br>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 |
|---|---|---|---|
| **apixaban vs placebo** | | | |
| APPRAISE 2 , 2011<br>[NCT00831441]<br>n=3705/3687<br>follow-up: 8 months | apixaban 5mg twice daily<br>versus<br>placebo | patients with a recent acute coronary syndrome and at least two additional risk factors for recurrent ischemic events | Parallel groups<br>double blind<br>39 countries |
| APPRAISE-1 (10mg od) , 2009<br>[NCT00313300]<br>n=318/611<br>follow-up: 6 months | apixaban 10 mg once daily<br>versus<br>placebo | patients with a recent ST-elevation or nonST-elevation acute coronary syndrome(<7 days) | Parallel groups<br>double blind<br>Europe, Middle East, North America |
| APPRAISE-1 (2.5 mg bid) , 2009<br>[NCT00313300 ]<br>n=NA<br>follow-up: 6 months | Apixaban 2.5mg twice daily<br>versus<br>placebo | patients with a recent ST-elevation or nonST-elevation acute coronary syndrome(<7 days) | double blind<br>Europe, Middle East, North America |

continued...

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

**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

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

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.