

# Clinical trials of antithrombotics for atrial fibrillation in secondary prevention of thromboembolic events

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## 1 anticoagulant

| Trial   | Treatments   | Patients  | Trials design and methods       |
|---|--|---|---------------------------------|
| <b>oral anticoagulant vs placebo</b>  |  |   |                                 |
| <b>EAFIT , 1993</b><br>n=225/214<br>follow-up: 2.3 years                      | Oral anticoagulation standard dose(target INR 3.0 (2.5-4.0)) the choice of anticoagulant type was free but most physicians choose coumarin derivatives.<br>versus<br>placebo | Patient with non rheumatic AF and recent TIA or minor ischaemic stroke(secondary prevention). | Parallel groups<br>Open         |
| <b>dabigatran 100mg vs warfarin</b>   |  |   |                                 |
| <b>RE-LY 110mg (2nd prevention subgroup) , 2010</b><br>n=NA<br>follow-up: 2 y | dabigatran 110mg daily<br>versus<br>warfarin   | patients with a prior stroke or transient ischemic attack                                     | Parallel groups<br>open         |
| <b>dabigatran 150mg vs warfarin</b>   |  |   |                                 |
| <b>RE-LY 150mg (2nd prevention subgroup)</b><br>n=NA<br>follow-up: 2 y        | dabigatran 150mg daily<br>versus<br>warfarin   | patients with a prior stroke or transient ischemic attack                                     | Parallel groups<br>open         |
| <b>rivaroxaban vs warfarin</b>  |  |   |                                 |
| <b>ROCKET (2nd prevention subgroup) , 2011</b><br>n=3892/3875<br>follow-up:   | rivaroxaban<br>versus<br>warfarin INR 2-3  | patients with a prior stroke or transient ischemic attack                                     | Parallel groups<br>double-blind |

## References

### EAFIT, 1993:

Secondary prevention in non-rheumatic atrial fibrillation after transient ischaemic attack or minor stroke. EAFIT (European Atrial Fibrillation Trial) Study Group. Lancet. 1993 Nov 20;342(8882):1255-62 [[7901582](#)]

### RE-LY 110mg (2nd prevention subgroup) , 2010:

1.Diener HC, Connolly S, Ezekowitz MD, et al. Dabigatran compared to warfarin in patients with atrial fibrillation and prior TIA or stroke: Results of RE-LY American Stroke Association International Stroke Conference 2010; February 26, 2010; San Antonio, TX. Abstract 195

### RE-LY 150mg (2nd prevention subgroup) , :

1.Diener HC, Connolly S, Ezekowitz MD, et al. Dabigatran compared to warfarin in patients with atrial fibrillation and prior TIA or stroke: Results of RE-LY American Stroke Association International Stroke Conference 2010; February 26, 2010; San Antonio, TX. Abstract 195

### ROCKET (2nd prevention subgroup) , 2011:

## 2 platelet aggregation inhibitors

| Trial  | Treatments   | Patients  | Trials design and methods                        |
|--|--|---|--|
| <b>aspirin vs placebo</b>  |  |   |  |
| <b>EAFT , 1993</b><br>n=404/378<br>follow-up: 2.3 years                  | aspirin 300 mg/d<br>versus<br>placebo  | Patient with non rheumatic AF and recent TIA or minor ischaemic stroke(secondary prevention). | Parallel groups<br>Double blind<br>europe,israel |
| <b>aspirin vs placebo (on top fluidione)</b>                             |  |   |  |
| <b>FFAACS , 2001</b><br>n=76/81<br>follow-up: 0.84 y                     | fluidione standard dose (target INR: 2-2.6) + aspirin low dose 100 mg<br>versus<br>fluidione standard dose(target INR:2-2.6) + placebo           | high risk patients with non valvular atrial fibrillation                                      | Parallel groups<br>Double blind<br>France        |
| <b>Indobufen vs warfarin</b>   |  |   |  |
| <b>SIFA , 1997</b><br>[NCT00244426]<br>n=462/454<br>follow-up: 12 months | indobufen 200 mg (the dose was lowered to 100 mg if impaired renal function:cc<80 ml/mn)<br>versus<br>warfarin standard dose(target INR 2.0-3.5) | non rheumatismal AF and recent cerebral ischemic episode(<or =15 days)                        | Parallel groups<br>Open<br>Italy                 |

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## References

### EAFT, 1993:

Secondary prevention in non-rheumatic atrial fibrillation after transient ischaemic attack or minor stroke. EAFT (European Atrial Fibrillation Trial) Study Group. Lancet. 1993 Nov 20;342(8882):1255-62 [[7901582](#)]

### FFAACS , 2001:

Lechat P, Lardoux H, Mallet A, Sanchez P, Derumeaux G, Lecompte T, Maillard L, Mas JL, Mentre F, Pousset F, Lacomblez L, Pisica G, Solbes-Latourette S, Raynaud P, Chaumet-Riffaud P Anticoagulant (fluidione)-aspirin combination in patients with high-risk atrial fibrillation. A randomized trial (Fluidione, Fibrillation Auriculaire, Aspirin et Contraste Spontane; FFAACS). Cerebrovasc Dis 2001;12:245-52 [[11641591](#)]

### SIFA, 1997:

Morocutti C, Amabile G, Fattapposta F, Nicolosi A, Matteoli S, Trappolini M, Cataldo G, Milanese G, Lavezzari M, Pamparana F, Coccheri S Indobufen versus warfarin in the secondary prevention of major vascular events in nonrheumatic atrial fibrillation. SIFA (Studio Italiano Fibrillazione Atriale) Investigators. Stroke 1997 May;28:1015-21 [[9158644](#)]

## 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.

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