

# Clinical trials of cholesterol lowering intervention for acute coronary syndrome in early initiation

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## 1 ezetimibe

| Trial                                                                             | Treatments                                                                             | Patients                                                   | Trials design and methods                       |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|------------------------------------------------------------|-------------------------------------------------|
| <b>ezetimibe vs control</b>                                                       |                                                                                        |                                                            |                                                 |
| <b>IMPROVE-IT , 2014</b><br>[NCT00202878]<br>n=9067/9077<br>follow-up: 5.68 years | 10 mg/day of ezetimibe and 40 mg/day of simvastatin<br>versus<br>simvastatin 40 mg/day | subjects with stabilized high-risk acute coronary syndrome | Parallel groups<br>double blind<br>39 countries |

## References

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## 2 statins

| Trial                                                                         | Treatments                                                  | Patients                                                                              | Trials design and methods                                                               |
|-------------------------------------------------------------------------------|-------------------------------------------------------------|---------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| <b>atorvastatin vs placebo</b>                                                |                                                             |                                                                                       |                                                                                         |
| <b>MIRACL , 2001</b><br>n=1538/1548<br>follow-up: 1 and 4 months              | Atorvastatin, 80 mg (early initiation)<br>versus<br>Placebo | unstable angina or nonQ-wave acute MI                                                 | Parallel groups<br>Double blind<br>Europe, North America, South Africa, and Australasia |
| <b>fluvastatin vs placebo</b>                                                 |                                                             |                                                                                       |                                                                                         |
| <b>LIPS (sub groups) , 2002</b><br>n=417/407<br>follow-up: 1, 4, and 6 months | Fluvastatin, 80 mg<br>versus<br>Placebo                     | patients with unstable angina and successful first percutaneous coronary intervention | Parallel groups<br>double blind<br>Europe, Canada, and Brazil                           |
| <b>FLORIDA , 2002</b><br>n=265/275<br>follow-up: 1, 4, and 6 months           | Fluvastatin, 80 mg (early initiation)<br>versus<br>Placebo  | patients with an AMI and total cholesterol of <6.5 mmol.l                             | Parallel groups<br>double blind<br>The Netherlands                                      |

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| <b>Trial</b>                                                                      | <b>Treatments</b>                                                                         | <b>Patients</b>                                                                                                                                                       | <b>Trials design and methods</b>                   |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| <b>Czech trial</b> <i>ongoing</i><br>[NCT00171275]<br>n=NA<br>follow-up: 52 weeks | fluvastatin<br>versus<br>placebo                                                          | -                                                                                                                                                                     | Parallel groups<br>double blind                    |
| <b>pravastatin vs placebo</b>                                                     |                                                                                           |                                                                                                                                                                       |                                                    |
| <b>LAMIL</b> , 1997<br>n=36/33<br>follow-up: 1 and 3 months                       | Pravastatin, 10-20 mg (starting at D3)<br>versus<br>Placebo                               | patients suffering an acute myocardial infarction                                                                                                                     | Parallel groups<br>double blind<br>Belgium         |
| <b>RECIFE</b> , 1999<br>n=30/30<br>follow-up: 1.5 months                          | Pravastatin, 40 mg<br>versus<br>Placebo                                                   | Patients with acute myocardial infarction or unstable angina and total cholesterol levels at admission $\geq 5.2$ mmol/L or LDL $\geq 3.4$ mmol/L                     | Parallel groups<br>double blind<br>Canada          |
| <b>PAIS</b> , 2001<br>n=50/49<br>follow-up: 1 and 3 months                        | Pravastatin, 40 mg (initiated within 48 hours of hospital admission)<br>versus<br>Placebo | patients with acute coronary syndromes                                                                                                                                | Parallel groups<br>double blind<br>The Netherlands |
| <b>PACT</b> , 2004<br>n=1710/1698<br>follow-up: 1 months                          | Pravastatin, 20-40 mg within 24 hours of the onset of symptoms in<br>versus<br>Placebo    | patients with unstable angina, non-ST-segment elevation myocardial infarction, or ST-segment elevation myocardial infarction within 24 hours of the onset of symptoms | Parallel groups<br>double blind<br>Australia       |
| <b>simvastatin vs placebo</b>                                                     |                                                                                           |                                                                                                                                                                       |                                                    |
| <b>A to Z</b> , 2004<br>n=2265/2232<br>follow-up: 4 months                        | Simvastatin, 40-80 mg early initiation<br>versus<br>Placebo                               | patient with an acute coronary syndrome (ACS)                                                                                                                         | Parallel groups<br>Double aveugle<br>41 countries  |
| <b>atorvastatin vs usual care</b>                                                 |                                                                                           |                                                                                                                                                                       |                                                    |
| <b>Colivicchi</b> , 2002<br>n=40/41<br>follow-up: 1, 3, and 6 months              | Atorvastatin, 80 mg daily early initiation<br>versus<br>Usual care                        | unstable angina pectoris or non-Q-wave myocardial infarction                                                                                                          | Parallel groups<br>open<br>Italy                   |
| <b>ESTABLISH</b> , 2004<br>n=35/35<br>follow-up: 1, 4, and 6 months               | Atorvastatin, 20 mg early initiation<br>versus<br>Usual care                              | patients with ACS undergoing emergency coronary angiography and percutaneous coronary intervention                                                                    | Parallel groups<br>open<br>Japan                   |
| <b>pravastatin vs usual care</b>                                                  |                                                                                           |                                                                                                                                                                       |                                                    |
| <b>L-CAD</b> , 2000<br>n=70/56<br>follow-up: 1, 4, and 6 months                   | Pravastatin, 20-40 mg (strating on average at D6)<br>versus<br>Usual care                 | patients with acute coronary syndrome                                                                                                                                 | Parallel groups<br>open<br>Germany                 |
| <b>PTT</b> , 2002<br>n=79/85<br>follow-up: 1 and 6 months                         | Pravastatin, 40 mg<br>versus<br>Usual care                                                | patients who underwent coronary balloon angioplasty of the infarct-related artery during the first month of acute myocardial infarction                               | Parallel groups<br>open<br>Turkey                  |

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| Trial                                                                          | Treatments                                                                                                     | Patients                                                                                              | Trials design and methods                                                                      |
|--------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| <b>pitavastatin vs atorvastatin</b>                                            |                                                                                                                |                                                                                                       |                                                                                                |
| <b>JAPAN ACS , 2009</b><br>[NCT00242944]<br>n=307<br>follow-up: 8-12 months    | pitavastatin 4 mg daily<br>versus<br>atorvastatin 20mg daily                                                   | patients with acute coronary syndrome<br>undergoing IVUS-guided percutaneous<br>coronary intervention | Parallel groups<br>open<br>Japan                                                               |
| <b>atorvastatin vs pravastatin</b>                                             |                                                                                                                |                                                                                                       |                                                                                                |
| <b>PROVE IT - TIMI 22 , 2004</b><br>n=2099/2063<br>follow-up: 24 mo (18-36 mo) | 80 mg of atorvastatin daily (intensive<br>therapy).<br>versus<br>40 mg of pravastatin daily (standard therapy) | patients who had been hospitalized for an<br>acute coronary syndrome within the<br>preceding 10 days  | Parallel groups<br>double blind<br>UK, US, AUstralia, Italy, France, Germany,<br>Spain, Canada |

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### 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.

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