

# Clinical trials of PCI with or without stent

TrialResults-center [www.trialresultscenter.org](http://www.trialresultscenter.org)

## 1 stable angina

| Trial  | Treatments  | Patients  | Trials design and methods             |
|--|---|---|---------------------------------------|
| <b>PCI with or without stent vs medical treatment</b>                            |   |   |                                       |
| <b>TIME , 2001</b><br>n=NA<br>follow-up:   | coronary angiography and revascularisation<br>versus<br>optimised medical therapy         | patients aged 75 years or older with chronic angina of at least Canadian Cardiac Society class II despite at least two antianginal drugs                            | Parallel groups<br>open               |
| <b>AVERT , 1995</b><br>n=177/164<br>follow-up: 1.5y                              | angioplasty<br>versus<br>atorvastatin at 80 mg per day                                    | Angina or asymptomatic, MI or unstable angina but not within 14 days, no triple vessel disease  | Parallel groups<br>open               |
| <b>Dakik , 1998</b><br>n=19/22<br>follow-up: 1y                                  | PTCA<br>versus<br>intensive medical therapy   | stable survivors of AMI   | Parallel groups<br>open               |
| <b>MASS II , 2007</b><br>n=205/203<br>follow-up: 5y                              | PCI<br>versus<br>medical therapy  | patients with multivessel coronary artery disease with stable angina and preserved ventricular function   | Parallel groups<br>open               |
| <b>COURAGE , 2007</b><br>[NCT00007657]<br>n=1149/1138<br>follow-up: median 4.6 y | PCI coupled with optimal medical therapy<br>versus<br>optimal medical therapy alone       | patients with stable coronary artery disease  | Parallel groups<br>open<br>Canada, US |
| <b>ALKK , 2003</b><br>n=149/151<br>follow-up: 4.7y                               | angioplasty<br>versus<br>medical therapy  | patients with single vessel disease of the infarct vessel and no or minor angina pectoris in the subacute phase (1 to 6 weeks) after an acute myocardial infarction | Parallel groups<br>open<br>Germany    |
| <b>Hambrecht , 2004</b><br>n=50/51<br>follow-up: 1y                              | PCI<br>versus<br>12 months of exercise training (20 minutes of bicycle ergometry per day) | male patients aged 70 years   | Parallel groups<br>open               |
| <b>Bech , 2001</b><br>n=90/91<br>follow-up: 2y                                   | PTCA<br>versus<br>deferral of PTCA  | patients with planned PTCA and no documented ischemia and with coronary pressure-derived fractional flow reserve >0.75  | Parallel groups<br>open               |

continued...

| Trial   | Treatments   | Patients  | Trials design and methods     |
|---|--|---|-------------------------------|
| ISCHEMIA <i>ongoing</i><br>n=NA<br>follow-up: | invasive strategy, consisting of early routine cardiac catheterization followed by revascularization plus optimal medical therapy (OMT) and lifestyle changes versus conservative strategy of optimal medical therapy and lifestyle changes in which invasive procedures will be performed only after failure of OMT | patients with stable ischemic heart disease and moderate to severe ischemia | Parallel groups<br>open-label |

More details and results :

- myocardial revascularization for stable angina in all type of patient at <http://www.trialresultscenter.org/go-Q25>
- myocardial revascularization for stable angina in single vessel disease at <http://www.trialresultscenter.org/go-Q27>
- myocardial revascularization for stable angina in multivessels disease at <http://www.trialresultscenter.org/go-Q28>

## References

### TIME, 2001:

Trial of invasive versus medical therapy in elderly patients with chronic symptomatic coronary-artery disease (TIME): a randomised trial. *Lancet* 2001;358:951-7 [[11583747](#)]

Masson C, Pruvo JP, Meder JF, Cordonnier C, Touz E, De La Sayette V, Giroud M, Mas JL, Leys D Spinal cord infarction: clinical and magnetic resonance imaging findings and short term outcome. *J Neurol Neurosurg Psychiatry* 2004;75:1431-5 [[15377691](#)]

Pfisterer M, Buser P, Osswald S, Allemann U, Amann W, Angehrn W, Eeckhout E, Erne P, Estlinbaum W, Kuster G, Moccetti T, Naegeli B, Rickenbacher P Outcome of elderly patients with chronic symptomatic coronary artery disease with an invasive vs optimized medical treatment strategy: one-year results of the randomized TIME trial. *JAMA* 2003;289:1117-23 [[12622581](#)]

### AVERT, 1995:

Pitt B, Waters D, Brown WV, van Boven AJ, Schwartz L, Title LM, Eisenberg D, Shurzinske L, McCormick LS Aggressive lipid-lowering therapy compared with angioplasty in stable coronary artery disease. Atorvastatin versus Revascularization Treatment Investigators *N Engl J Med* 1999;341:70-6 [[10395630](#)]

### Dakik, 1998:

Dakik HA, Kleiman NS, Farmer JA, He ZX, Wendt JA, Pratt CM, Verani MS, Mahmarian JJ Intensive medical therapy versus coronary angioplasty for suppression of myocardial ischemia in survivors of acute myocardial infarction: a prospective, randomized pilot study *Circulation* 1998;98:2017-23 [[9808599](#)]

### MASS II, 2007:

Hueb W, Lopes NH, Gersh BJ, Soares P, Machado LA, Jatene FB, Oliveira SA, Ramires JA Five-year follow-up of the Medicine, Angioplasty, or Surgery Study (MASS II): a randomized controlled clinical trial of 3 therapeutic strategies for multivessel coronary artery disease *Circulation* 2007;115:1082-9 [[17339566](#)] [10.1161/CIRCULATIONAHA.106.625475](#)

Hueb W, Soares PR, Gersh BJ, Csar LA, Luz PL, Puig LB, Martinez EM, Oliveira SA, Ramires JA The medicine, angioplasty, or surgery study (MASS-II): a randomized, controlled clinical trial of three therapeutic strategies for multivessel coronary artery disease: one-year results. J Am Coll Cardiol 2004;43:1743-51 [15145093]

Hueb W, Lopes N, Gersh BJ, Soares PR, Ribeiro EE, Pereira AC, Favarato D, Rocha AS, Hueb AC, Ramires JA Ten-year follow-up survival of the Medicine, Angioplasty, or Surgery Study (MASS II): a randomized controlled clinical trial of 3 therapeutic strategies for multivessel coronary artery disease. Circulation 2010;122:949-57 [20733102] 10.1161/CIRCULATIONAHA.109.911669

#### **COURAGE, 2007:**

Boden WE, O'Rourke RA, Teo KK, Hartigan PM, Maron DJ, Kostuk WJ, Knudtson M, Dada M, Casperson P, Harris CL, Chaitman BR, Shaw L, Gosselin G, Nawaz S, Title LM, Gau G, Blaustein AS, Booth DC, Bates ER, Spertus JA, Berman DS, Mancini GB, Weintraub WS Optimal medical therapy with or without PCI for stable coronary disease. N Engl J Med 2007 Apr 12;356:1503-16 [17387127]

#### **ALKK, 2003:**

Zeymer U, Uebis R, Vogt A, Glunz HG, Vhringer HF, Harmjanz D, Neuhaus KL Randomized comparison of percutaneous transluminal coronary angioplasty and medical therapy in stable survivors of acute myocardial infarction with single vessel disease: a study of the Arbeitsgemeinschaft Leitende Kardiologische Krankenhausrzte Circulation 2003;108:1324-8 [12939210] 10.1161/01.CIR.0000087605.09362.0E

#### **Hambrecht, 2004:**

Hambrecht R, Walther C, Mbius-Winkler S, Gielen S, Linke A, Conradi K, Erbs S, Kluge R, Kendziorra K, Sabri O, Sick P, Schuler G Percutaneous coronary angioplasty compared with exercise training in patients with stable coronary artery disease: a randomized trial Circulation 2004;109:1371-8 [15007010] 10.1161/01.CIR.0000121360.31954.1F

#### **Bech, 2001:**

Bech GJ, De Bruyne B, Pijls NH, de Muinck ED, Hoorntje JC, Escaned J, Stella PR, Boersma E, Bartunek J, Koolen JJ, Wijns W Fractional flow reserve to determine the appropriateness of angioplasty in moderate coronary stenosis: a randomized trial Circulation 2001;103:2928-34 [11413082]

#### **ISCHEMIA, :**

ongoing trial

## 2 coronary artery disease

| Trial   | Treatments  | Patients   | Trials design and methods |
|---|---|--|---------------------------|
| <b>PCI with or without stent vs medical treatment</b> |   |  |                           |
| <b>TIME , 2001</b><br>n=NA<br>follow-up:              | coronary angiography and revascularisation<br>versus<br>optimised medical therapy | patients aged 75 years or older with chronic angina of at least Canadian Cardiac Society class II despite at least two antianginal drugs | Parallel groups<br>open   |
| <b>AVERT , 1995</b><br>n=177/164<br>follow-up: 1.5y   | angioplasty<br>versus<br>atorvastatin at 80 mg per day                            | Angina or asymptomatic, MI or unstable angina but not within 14 days, no triple vessel disease   | Parallel groups<br>open   |
| <b>Dakik , 1998</b><br>n=19/22<br>follow-up: 1y       | PTCA<br>versus<br>intensive medical therapy                                       | stable survivors of AMI  | Parallel groups<br>open   |

continued...

| <b>Trial</b>   | <b>Treatments</b>  | <b>Patients</b>   | <b>Trials design and methods</b>      |
|--|--|---|---------------------------------------|
| <b>MASS II , 2007</b><br>n=205/203<br>follow-up: 5y                              | PCI<br>versus<br>medical therapy   | patients with multivessel coronary artery disease with stable angina and preserved ventricular function   | Parallel groups<br>open               |
| <b>COURAGE , 2007</b><br>[NCT00007657]<br>n=1149/1138<br>follow-up: median 4.6 y | PCI coupled with optimal medical therapy<br>versus<br>optimal medical therapy aloneitm   | patients with stable coronary artery disease  | Parallel groups<br>open<br>Canada, US |
| <b>ALKK , 2003</b><br>n=149/151<br>follow-up: 4.7y                               | angioplasty<br>versus<br>medical therapy   | patients with single vessel disease of the infarct vessel and no or minor angina pectoris in the subacute phase (1 to 6 weeks) after an acute myocardial infarction | Parallel groups<br>open<br>Germany    |
| <b>Hambrecht , 2004</b><br>n=50/51<br>follow-up: 1y                              | PCI<br>versus<br>12 months of exercise training (20 minutes of bicycle ergometry per day)  | male patients aged 70 years   | Parallel groups<br>open               |
| <b>Bech , 2001</b><br>n=90/91<br>follow-up: 2y                                   | PTCA<br>versus<br>deferral of PTCA   | patients with planned PTCA and no documented ischemia and with coronary pressurederived fractional flow reserve >0.75   | Parallel groups<br>open               |
| <b>ISCHEMIA</b> <i>ongoing</i><br>n=NA<br>follow-up:                             | invasive strategy, consisting of early routine cardiac catheterization followed by revascularization plus optimal medical therapy (OMT) and lifestyle changes<br>versus<br>conservative strategy of optimal medical therapy and lifestyle changes in which invasive procedures will be performed only after failure of OMT | patients with stable ischemic heart disease and moderate to severe ischemia   | Parallel groups<br>open-label         |

More details and results :

- myocardial revascularization for coronary artery disease in all type of patient at <http://www.trialresultscenter.org/go-Q26>

## References

### TIME, 2001:

Trial of invasive versus medical therapy in elderly patients with chronic symptomatic coronary-artery disease (TIME): a randomised trial. *Lancet* 2001;358:951-7 [11583747]

Masson C, Pruvo JP, Meder JF, Cordonnier C, Touz E, De La Sayette V, Giroud M, Mas JL, Leys D Spinal cord infarction: clinical and magnetic resonance imaging findings and short term outcome. *J Neurol Neurosurg Psychiatry* 2004;75:1431-5 [15377691]

Pfisterer M, Buser P, Osswald S, Allemann U, Amann W, Angehrn W, Eeckhout E, Erne P, Estlinbaum W, Kuster G, Moccetti T, Naegeli B, Rickenbacher P Outcome of elderly patients with chronic symptomatic coronary artery disease with an invasive vs optimized medical treatment strategy: one-year results of the randomized TIME trial. *JAMA* 2003;289:1117-23 [[12622581](#)]

#### **AVERT, 1995:**

Pitt B, Waters D, Brown WV, van Boven AJ, Schwartz L, Title LM, Eisenberg D, Shurzinske L, McCormick LS Aggressive lipid-lowering therapy compared with angioplasty in stable coronary artery disease. Atorvastatin versus Revascularization Treatment Investigators *N Engl J Med* 1999;341:70-6 [[10395630](#)]

#### **Dakik, 1998:**

Dakik HA, Kleiman NS, Farmer JA, He ZX, Wendt JA, Pratt CM, Verani MS, Mahmarian JJ Intensive medical therapy versus coronary angioplasty for suppression of myocardial ischemia in survivors of acute myocardial infarction: a prospective, randomized pilot study *Circulation* 1998;98:2017-23 [[9808599](#)]

#### **MASS II, 2007:**

Hueb W, Lopes NH, Gersh BJ, Soares P, Machado LA, Jatene FB, Oliveira SA, Ramires JA Five-year follow-up of the Medicine, Angioplasty, or Surgery Study (MASS II): a randomized controlled clinical trial of 3 therapeutic strategies for multivessel coronary artery disease *Circulation* 2007;115:1082-9 [[17339566](#)] [10.1161/CIRCULATIONAHA.106.625475](#)

Hueb W, Soares PR, Gersh BJ, Csar LA, Luz PL, Puig LB, Martinez EM, Oliveira SA, Ramires JA The medicine, angioplasty, or surgery study (MASS-II): a randomized, controlled clinical trial of three therapeutic strategies for multivessel coronary artery disease: one-year results. *J Am Coll Cardiol* 2004;43:1743-51 [[15145093](#)]

Hueb W, Lopes N, Gersh BJ, Soares PR, Ribeiro EE, Pereira AC, Favarato D, Rocha AS, Hueb AC, Ramires JA Ten-year follow-up survival of the Medicine, Angioplasty, or Surgery Study (MASS II): a randomized controlled clinical trial of 3 therapeutic strategies for multivessel coronary artery disease. *Circulation* 2010;122:949-57 [[20733102](#)] [10.1161/CIRCULATIONAHA.109.911669](#)

#### **COURAGE, 2007:**

Boden WE, O'Rourke RA, Teo KK, Hartigan PM, Maron DJ, Kostuk WJ, Knudtson M, Dada M, Casperson P, Harris CL, Chaitman BR, Shaw L, Gosselin G, Nawaz S, Title LM, Gau G, Blaustein AS, Booth DC, Bates ER, Spertus JA, Berman DS, Mancini GB, Weintraub WS Optimal medical therapy with or without PCI for stable coronary disease. *N Engl J Med* 2007 Apr 12;356:1503-16 [[17387127](#)]

#### **ALKK, 2003:**

Zeymer U, Uebis R, Vogt A, Glunz HG, Vhringer HF, Harmjanz D, Neuhaus KL Randomized comparison of percutaneous transluminal coronary angioplasty and medical therapy in stable survivors of acute myocardial infarction with single vessel disease: a study of the Arbeitsgemeinschaft Leitende Kardiologische Krankenhausrzte *Circulation* 2003;108:1324-8 [[12939210](#)] [10.1161/01.CIR.0000087605.09362.0E](#)

#### **Hambrecht, 2004:**

Hambrecht R, Walther C, Mbius-Winkler S, Gielen S, Linke A, Conradi K, Erbs S, Kluge R, Kendziorra K, Sabri O, Sick P, Schuler G Percutaneous coronary angioplasty compared with exercise training in patients with stable coronary artery disease: a randomized trial *Circulation* 2004;109:1371-8 [[15007010](#)] [10.1161/01.CIR.0000121360.31954.1F](#)

#### **Bech, 2001:**

Bech GJ, De Bruyne B, Pijls NH, de Muinck ED, Hoorntje JC, Escaned J, Stella PR, Boersma E, Bartunek J, Koolen JJ, Wijns W Fractional flow reserve to determine the appropriateness of angioplasty in moderate coronary stenosis: a randomized trial *Circulation* 2001;103:2928-34 [[11413082](#)]

#### **ISCHEMIA, :**

ongoing trial

Entry terms: PCI