

# Clinical trials of invasive strategy

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## 1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
<b>invasive strategy vs conservative strategy</b>			
DANAMI , 1997 n=NA follow-up: 2.4y	invasive strategy of PTCA or CABG versus conservative strategy	patients who received thrombolytic treatment for a first acute myocardial infarction and with inducible myocardial ischemia (either symptomatic angina pectoris presenting spontaneously >36 hours after admission or during a pre-discharge exercise test or ST changes during exercise compatible with ischemia)	

More details and results :

- myocardial revascularization for acute myocardial infarction in patients with inducible post MI ischemia at <http://www.trialresultscenter.org/go-Q256>
- PCI for acute myocardial infarction in patients with inducible post MI ischemia at <http://www.trialresultscenter.org/go-Q257>

## References

### DANAMI, 1997:

Madsen JK, Grande P, Saunamki K, Thayssen P, Kassis E, Eriksen U, Rasmussen K, Hauns S, Nielsen TT, Haghfelt T, Fritz-Hansen P, Hjelms E, Paulsen PK, Alstrup P, Arendrup H, Niebuhr-Jrgensen U, Andersen LI Danish multicenter randomized study of invasive versus conservative treatment in patients with inducible ischemia after thrombolysis in acute myocardial infarction (DANAMI). DANish trial in Acute Myocardial Infarction. Circulation 1997 Aug 5;96:748-55 [9264478]

Madsen JK, Nielsen TT, Grande P, Eriksen UH, Saunamki K, Thayssen P, Kassis E, Rasmussen K, Hauns S, Haghfelt T, Fritz-Hansen P, Hjelms E, Paulsen PK, Alstrup P, Arendrup H, Niebuhr-Jrgensen U, Andersen LI Revascularization compared to medical treatment in patients with silent vs. symptomatic residual ischemia after thrombolysed myocardial infarction—the DANAMI study. Cardiology 2007;108:243-51 [17114878]

## 2 acute coronary syndrome

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>routine invasive strategy vs conservative strategy</b>			
<b>ICTUS , 2007</b> [ISRCTN82153174] n=604/596 follow-up: 12 mo (4y)	early invasive strategy versus selective invasive treatment strategy	patients with nonST-segment elevation acute coronary syndrome and elevated cardiac troponin T	Parallel groups open Netherlands
<b>FRISC 2 , 1999</b> n=1222/1234 follow-up: 24 mo	early invasive treatment strategy: angiography within 7 days aiming for revascularisation versus non-invasive treatment strategy: angiography only in patients with refractory or recurrent symptoms despite maximum medical treatment or severe ischemia during exercise test before discharge	patients with nonST-segment elevation acute coronary syndrome	Factorial plan Open Scandinavia
<b>NQWMI (Eisenberg) , 2005</b>  n=42/46 follow-up: 12 months	Invasive (angiography at days 2 to 5) versus Noninvasive (stress testing at day 2 to 5)	patients with nonQ-wave myocardial infarction	Parallel groups open Canada
<b>RITA 3 , 2002</b> [ISRCTN07752711r] n=895/915 follow-up: 24 mo (60 mo)	routine angiography followed by revascularisation versus conservative strategy (ischaemia-driven or symptom-driven angiography)	patients with nonST-segment elevation acute coronary syndrome	Parallel groups open UK
<b>TACTICS-TIMI 18 , 2001</b> n=1114/1106 follow-up: 6 mo	early invasive management strategy versus conservative management strategy	patients with nonST-segment elevation acute coronary syndrome	Parallel groups open 9 countries
<b>TRUCS , 2000</b> n=76/72 follow-up: 12 mo	invasive strategy versus conservative strategy	patients with nonST-segment elevation acute coronary syndrome in geographically isolated hospitals without cardiac surgical facilities	Parallel groups Greece
<b>VINO , 2002</b> n=64/67 follow-up: 6 mo	first day angiography / angioplasty strategy versus early conservative therapy	patients with nonST-segment elevation acute coronary syndrome	Parallel groups open Czech Republic
<b>TACTICS-TIMI 18 elderly (sub group) , 2001</b> n=491/471 follow-up: 6 mo	early invasive management strategy versus conservative management strategy	patients 65 years of age and older with unstable angina and nonSTsegment elevation myocardial infarction	open 9 countries

continued...

Trial	Treatments	Patients	Trials design and methods
the Italian Elderly ACS study <i>ongoing</i> [NCT00510185] n=NA follow-up:	early aggressive approach versus initially conservative approach	patients older than 74 years of age with NSTEACS	
<b>routine invasive strategy - noncontemporary vs conservative strategy</b>			
MATE , 1998 n=111/90 follow-up: 21 mo	early triage angiography and subsequent therapies based on the angiogram versus conventional medical therapy	acute MI ineligible for thrombolytic therapy within 24 h of symptoms	Parallel groups open US
TIMI 3B (PTCA) , 1994 n=740/733 follow-up: 12 mo	Early invasive strategy: systematic angiography (18-48h after randomisation) and revascularisation (PTCA or CABG) versus Early elective strategy: angiography and revascularisation only in case of ischemic recurrence (see paper)	patient with unstable angina or non Q wave MI within 24hrs of onset	Factorial plan Open USA & Canada
VANQWISH , 1998 n=462/458 follow-up: 23 mo	invasive management versus conservative management: medical therapy with subsequent invasive management if indicated by the development of spontaneous or inducible ischemia within 24-72 hours	Patients with NonQ-wave myocardial infarction	Parallel groups Open US

More details and results :

- myocardial revascularization for acute coronary syndrome in all type of patients at <http://www.trialresultscenter.org/go-Q22>
- myocardial revascularization for acute coronary syndrome in Elderly patients at <http://www.trialresultscenter.org/go-Q165>

## References

### ICTUS, 2007:

Hirsch A, Windhausen F, Tijssen JG, Verheugt FW, Cornel JH, de Winter RJ Long-term outcome after an early invasive versus selective invasive treatment strategy in patients with non-ST-elevation acute coronary syndrome and elevated cardiac troponin T (the ICTUS trial): a follow-up study. *Lancet* 2007;369:827-35 [[17350451](#)]

de Winter RJ, Windhausen F, Cornel JH, Dunselman PH, Janus CL, Bendermacher PE, Michels HR, Sanders GT, Tijssen JG, Verheugt FW Early invasive versus selectively invasive management for acute coronary syndromes. *N Engl J Med* 2005;353:1095-104 [[16162880](#)]

### FRISC 2, 1999:

Invasive compared with non-invasive treatment in unstable coronary-artery disease: FRISC II prospective randomised multicentre study. FRagmin and Fast Revascularisation during InStability in Coronary artery disease Investigators. *Lancet* 1999;354:708-15 [[10475181](#)]

Lagerqvist B, Husted S, Kontny F, Stahle E, Swahn E, Wallentin L 5-year outcomes in the FRISC-II randomised trial of an invasive versus a non-invasive strategy in non-ST-elevation acute coronary syndrome: a follow-up study. *Lancet* 2006;368:998-1004 [[16980115](#)]

Lagerqvist B, Husted S, Kontny F, Nslund U, Sthle E, Swahn E, Wallentin L A long-term perspective on the protective effects of an early invasive strategy in unstable coronary artery disease: two-year follow-up of the FRISC-II invasive study. *J Am Coll Cardiol* 2002;40:1902-14 [[12475448](#)]

Lagerqvist B, Husted S, Kontny F, Sthle E, Swahn E, Wallentin L 5-year outcomes in the FRISC-II randomised trial of an invasive versus a non-invasive strategy in non-ST-elevation acute coronary syndrome: a follow-up study. *Lancet* 2006 Sep 16;368:998-1004 [[16980115](#)]

#### **NQWMI (Eisenberg), 2005:**

Eisenberg MJ, Teng FF, Chaudhry MR, Ortiz J, Sobkowski W, Ebrahim I, Saligrama RS, Serio K, Lader E, Pilote L Impact of invasive management versus noninvasive management on functional status and quality of life following non-Q-wave myocardial infarction: a randomized clinical trial. *Am Heart J* 2005;149:813-9 [[15894961](#)]

#### **RITA 3, 2002:**

Fox KA, Poole-Wilson PA, Henderson RA, Clayton TC, Chamberlain DA, Shaw TR, Wheatley DJ, Pocock SJ Interventional versus conservative treatment for patients with unstable angina or non-ST-elevation myocardial infarction: the British Heart Foundation RITA 3 randomised trial. *Randomized Intervention Trial of unstable Angina. Lancet* 2002 Sep 7;360:743-51 [[12241831](#)]

Fox KA, Poole-Wilson P, Clayton TC, Henderson RA, Shaw TR, Wheatley DJ, Knight R, Pocock SJ 5-year outcome of an interventional strategy in non-ST-elevation acute coronary syndrome: the British Heart Foundation RITA 3 randomised trial. *Lancet* 2005;366:914-20 [[16154018](#)]

#### **TACTICS-TIMI 18, 2001:**

Cannon CP, Weintraub WS, Demopoulos LA, Vicari R, Frey MJ, Lakkis N, Neumann FJ, Robertson DH, DeLucca PT, DiBattiste PM, Gibson CM, Braunwald E Comparison of early invasive and conservative strategies in patients with unstable coronary syndromes treated with the glycoprotein IIb/IIIa inhibitor tirofiban. *N Engl J Med* 2001 Jun 21;344:1879-87 [[11419424](#)]

#### **TRUCS, 2000:**

Michalis LK, Stroumbis CS, Pappas K, Sourla E, Niokou D, Goudevenos JA, Siogas C, Sideris DA Treatment of refractory unstable angina in geographically isolated areas without cardiac surgery. Invasive versus conservative strategy (TRUCS study). *Eur Heart J* 2000;21:1954-9 [[11071801](#)]

#### **VINO, 2002:**

Spacek R, Widimsky P, Straka Z, Jiresova E, Dvorak J, Polasek R, Karel I, Jirmar R, Lisa L, Budesinsky T, Malek F, Stanka P Value of first day angiography/angioplasty in evolving Non-ST segment elevation myocardial infarction: an open multicenter randomized trial. The VINO Study. *Eur Heart J* 2002 Feb;23:230-8 [[11792138](#)]

#### **TACTICS-TIMI 18 elderly (sub group), 2001:**

Bach RG, Cannon CP, Weintraub WS, DiBattiste PM, Demopoulos LA, Anderson HV, DeLucca PT, Mahoney EM, Murphy SA, Braunwald E The effect of routine, early invasive management on outcome for elderly patients with non-ST-segment elevation acute coronary syndromes. *Ann Intern Med* 2004;141:186-95 [[15289215](#)]

#### **the Italian Elderly ACS study, 0:**

ongoing trial NCT00510185

Savonitto S, De Servi S, Petronio AS, Bolognese L, Cavallini C, Greco C, Indolfi C, Visconti LO, Piscione F, Ambrosio G, Galvani M, Marzocchi A, Santilli I, Steffenino G, Maseri A Early aggressive vs. initially conservative treatment in elderly patients with non-ST-elevation acute coronary syndrome: the Italian Elderly ACS study. *J Cardiovasc Med (Hagerstown)* 2008;9:217-26 [[18301136](#)]

#### **MATE, 1998:**

McCullough PA, O'Neill WW, Graham M, Stomel RJ, Rogers F, David S, Farhat A, Kazlauskaitė R, Al-Zagoum M, Grines CL A prospective randomized trial of

triage angiography in acute coronary syndromes ineligible for thrombolytic therapy. Results of the medicine versus angiography in thrombolytic exclusion (MATE) trial. J Am Coll Cardiol 1998 Sep;32:596-605 [[9741499](#)]

**TIMI 3B (PTCA), 1994:**

Effects of tissue plasminogen activator and a comparison of early invasive and conservative strategies in unstable angina and non-Q-wave myocardial infarction. Results of the TIMI IIIB Trial. Thrombolysis in Myocardial Ischemia. Circulation 1994;89:1545-56 [[8149520](#)]

**VANQWISH, 1998:**

Boden WE, O'Rourke RA, Crawford MH, Blaustein AS, Deedwania PC, Zoble RG, Wexler LF, Kleiger RE, Pepine CJ, Ferry DR, Chow BK, Lavori PW Outcomes in patients with acute non-Q-wave myocardial infarction randomly assigned to an invasive as compared with a conservative management strategy. Veterans Affairs Non-Q-Wave Infarction Strategies in Hospital (VANQWISH) Trial Investigators. N Engl J Med 1998;338:1785-92 [[9632444](#)] [10.1056/NEJM199806183382501](#)