

# Clinical trials of error

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

## 1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
<b>error vs control</b>			
<a href="#">Dekleva , 2004</a> n=NA	-	-	
<b>error vs error</b>			
<a href="#">Zharov , 1991</a> n=63/52 follow-up:	-	-	Parallel groups
<a href="#">RECOVER 2 , 2009</a> <i>ongoing</i> [NCT00972270] n=NA follow-up:	-	-	
<a href="#">COMPARE AMI</a> <i>ongoing</i> n=NA	-	-	
<a href="#">SWISS-AMI</a> <i>ongoing</i> n=NA	-	-	

More details and results :

- nitrates for acute myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q144>
- cell-based therapies for acute myocardial infarction in PCI at <http://www.trialresultscenter.org/go-Q313>
- percutaneous left ventricular assist devices for acute myocardial infarction in cardiogenic shock at <http://www.trialresultscenter.org/go-Q352>
- oxygen therapy for acute myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q429>

## References

Dekleva, 2004:

Stavitsky Y, Shandling AH, Ellestad MH, Hart GB, Van Natta B, Messenger JC, Strauss M, Dekleva MN, Alexander JM, Mattice M, Clarke D Hyperbaric oxygen and thrombolysis in myocardial infarction: the 'HOT MI' randomized multicenter study. *Cardiology* 1998;90:131-6 [9778551]

Shandling AH, Ellestad MH, Hart GB, Crump R, Marlow D, Van Natta B, Messenger JC, Strauss M, Stavitsky Y Hyperbaric oxygen and thrombolysis in myocardial infarction: the "HOT MI" pilot study. *Am Heart J* 1997;134:544-50 [9327714]

Dekleva M, Neskovic A, Vlahovic A, Putnikovic B, Beleslin B, Ostojic M. Adjunctive effect of hyperbaric oxygen treatment after thrombolysis on left ventricular function in patients with acute myocardial infarction *American Heart Journal* 2004;148:e14.

**Zharov, 1991:**

Zharov EI, Vertkin AL, Martynov AI, Salnikov SN *Cardiology* 1991;79(Suppl 2):639.e

**RECOVER 2, 2009:**

ongoing trial NCT00972270

Slaughter MS, Rogers JG, Milano CA, Russell SD, Conte JV, Feldman D, Sun B, Tatroles AJ, Delgado RM 3rd, Long JW, Wozniak TC, Ghumman W, Farrar DJ, Frazier OH Advanced heart failure treated with continuous-flow left ventricular assist device. *N Engl J Med* 2009 Dec 3;361:2241-51 [19920051]

**COMPARE AMI, :**

ongoing trial

Mansour S, Roy DC, Bouchard V, Nguyen BK, Stevens LM, Gobeil F, Rivard A, Leclerc G, Reeves F, Noiseux N COMPARE-AMI trial: comparison of intracoronary injection of CD133+ bone marrow stem cells to placebo in patients after acute myocardial infarction and left ventricular dysfunction: study rationale and design. *J Cardiovasc Transl Res* 2010;3:153-9 [20560029] [10.1007/s12265-009-9145-2](https://doi.org/10.1007/s12265-009-9145-2)

**SWISS-AMI, :**

ongoing trial

Srder D, Schwitter J, Moccetti T, Astori G, Rufibach K, Plein S, Lo Cicero V, Soncin S, Windecker S, Moschovitis A, Wahl A, Erne P, Jamshidi P, Auf der Maur C, Manka R, Soldati G, Bhler I, Wyss C, Landmesser U, Lscher TF, Corti R Cell-based therapy for myocardial repair in patients with acute myocardial infarction: rationale and study design of the SWiss multicenter Intracoronary Stem cells Study in Acute Myocardial Infarction (SWISS-AMI). *Am Heart J* 2010;160:58-64 [20598973] [10.1016/j.ahj.2010.03.039](https://doi.org/10.1016/j.ahj.2010.03.039)

## 2 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
<b>error vs error</b>			
JPPP <i>ongoing</i> [NCT00225849] n=NA follow-up:	aspirin versus no aspirin	Japanese patients aged 60 to 85 years with hypertension, dyslipidemia, or diabetes mellitus	Parallel groups open Japan
<b>error vs placebo</b>			
PHASE <i>ongoing</i> n=NA	-	-	

More details and results :

- antiplatelets drug for cardiovascular prevention in all type of patients at <http://www.trialresultscenter.org/go-Q226>
- antiplatelets drug for cardiovascular prevention in primary prevention at <http://www.trialresultscenter.org/go-Q322>
- antiplatelets drug for cardiovascular prevention in patients without established disease at <http://www.trialresultscenter.org/go-Q403>
- antithrombotics for cardiovascular prevention in primary prevention at <http://www.trialresultscenter.org/go-Q437>
- hormonal replacement therapy for cardiovascular prevention in all type of patients at <http://www.trialresultscenter.org/go-Q452>

## References

### JPPP, :

ongoing trial NCT00225849

Teramoto T, Shimada K, Uchiyama S, Sugawara M, Goto Y, Yamada N, Oikawa S, Ando K, Ishizuka N, Yamazaki T, Yokoyama K, Murata M, Ikeda Y Rationale, design, and baseline data of the Japanese Primary Prevention Project (JPPP)-a randomized, open-label, controlled trial of aspirin versus no aspirin in patients with multiple risk factors for vascular events. Am Heart J 2010;159:361-369.e4 [20211296] 10.1016/j.ahj.2009.11.030

### PHASE, :

ongoing trial

## 3 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
<b>error vs control</b>			
<a href="#">Dekleva , 2004</a> n=NA	-	-	

More details and results :

- oxygen therapy for acute coronary syndrome in all type of patients at <http://www.trialresultscenter.org/go-Q428>

## References

### Dekleva, 2004:

Stavitsky Y, Shandling AH, Ellestad MH, Hart GB, Van Natta B, Messenger JC, Strauss M, Dekleva MN, Alexander JM, Mattice M, Clarke D Hyperbaric oxygen and thrombolysis in myocardial infarction: the 'HOT MI' randomized multicenter study. Cardiology 1998;90:131-6 [9778551]

Shandling AH, Ellestad MH, Hart GB, Crump R, Marlow D, Van Natta B, Messenger JC, Strauss M, Stavitsky Y Hyperbaric oxygen and thrombolysis in myocardial infarction: the "HOT MI" pilot study. Am Heart J 1997;134:544-50 [9327714]

Dekleva M, Neskovic A, Vlahovic A, Putnikovic B, Beleslin B, Ostojic M. Adjunctive effect of hyperbaric oxygen treatment after thrombolysis on left ventricular function in patients with acute myocardial infarction American Heart Journal 2004;148:e14.

## 4 DVT prophylaxis

Trial	Treatments	Patients	Trials design and methods
<b>error vs placebo</b>			
Denver-I n=14/14	SP versus placebo	High risk medical patients	
Denver-II , 1980 n=19/19 follow-up: 18 months	dipyridamole 100 mg a day and aspirin 1200 mg a day versus placebo	patients with recurring venous thromboembolism	Parallel groups double-blind
Toulouse-II <i>unpublished</i> n=40/40 follow-up:	A990+Dip versus placebo	patients with stroke	Parallel groups double-blind
Den Ottolander , 1982 n=14/14 follow-up:	A1500+RA233 versus placebo	patients with decompensated heart disease	
GRAND , 1987 <i>unpublished</i> n=63/64 follow-up:	GR32191B versus placebo	High risk medical patients	
Jones , 1987 <i>unpublished</i> n=60/60 follow-up:	Dazoxidben versus placebo	High risk medical patients	

More details and results :

- antithrombotics for DVT prophylaxis in medical patients at <http://www.trialresultscenter.org/go-Q87>
- antiplatelets drug for DVT prophylaxis in medical patients at <http://www.trialresultscenter.org/go-Q463>

## References

### Denver-I , :

Steele P, Ellis J, Genton E. Effects of platelet suppressant, anticoagulant and fibrinolytic therapy in recurrent venous thrombosis Clin Res 1976;24: abstract 573.

### Denver-II , 1980:

Steele P Trial of dipyridamole-aspirin in recurring venous thrombosis. Lancet 1980;2:1328-9 [6109150]

### Toulouse-II , 0:

unpublished

Pince J. Thromboses veineuses des membres inférieurs et embolies pulmonaires au cours des accidents vasculaires cérébraux. A propos d'un essai comparatif de traitement préventif These pour le doctorat d'état en médecine. Toulouse: Université Paul Sabatier, 1981.

### Den Ottolander , 1982:

Den Ottolander GJH, van der Maas APC, Veen MR. The preventive value against venous thrombosis by treatment with ASA and RA-233 in patients with decompensated heart disease In: Proceedings of III congress of International Society for Thrombosis and Haemostasis. (Washington). 1972:40.

### GRAND , 1987:

unpublished

Glaxo. GRAND (Glaxo receptor antagonist against Nottingham DVI). Uxbridge: Glaxo, 1987

### Jones , 1987:

unpublished

Jones EW. A study of dazoxiben in the prevention of venous thrombosis after suspected myocardial infarction (MD thesis) Nottingham: Nottingham University, 1987.

## 5 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
<b>error vs placebo</b>			
<b>Pan , 2003</b> n=261 follow-up: 16 weeks	acarbose 50 mg three times daily versus placebo	patients with impaired glucose tolerance (American Diabetes Association 1997 criteria)	Parallel groups double blind China
<b>STOP-NIDDM (Chiasson) , 2002</b> n=714/715 follow-up: 3.3 years	acarbose 100mg three times daily versus placebo	patients with impaired glucose tolerance (WHO 1985 criteria)	Parallel groups double blind Canada, Germany, Austria, Nordic countries, Spain, Israel
<b>error vs placebo (add on to met)</b>			
<b>Halimi , 2000</b> n=74/78 follow-up: 26 weeks	acarbose titrated up to 100 mg three times daily versus placebo	patients with Type 2 diabetes and inadequately controlled with metformin monotherapy	Parallel groups double-blind

continued...

Trial	Treatments	Patients	Trials design and methods
Rosenstock , 1998 n=74/74 follow-up: 24 weeks	acarbose forced titration from 25-50 mg t.i.d. and a titration of 50-100 mg tid that was based on glucose control versus placebo	patients with type 2 diabetes inadequately controlled with diet and metformin (2,000 or 2,500 mg/day in divided doses	Parallel groups double-blind

More details and results :

- prevention for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q341>
- alpha-glucosidase inhibitors for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q379>
- prevention for diabetes type 2 in people with impaired glucose tolerance at <http://www.trialresultscenter.org/go-Q416>

## References

### Pan, 2003:

Pan CY, Gao Y, Chen JW, Luo BY, Fu ZZ, Lu JM, Guo XH, Cheng H Efficacy of acarbose in Chinese subjects with impaired glucose tolerance. Diabetes Res Clin Pract 2003;61:183-90 [[12965108](#)]

### STOP-NIDDM (Chiasson), 2002:

Chiasson JL, Josse RG, Gomis R, Hanefeld M, Karasik A, Laakso M Acarbose for prevention of type 2 diabetes mellitus: the STOP-NIDDM randomised trial. Lancet 2002;359:2072-7 [[12086760](#)]

Chiasson JL, Josse RG, Gomis R, Hanefeld M, Karasik A, Laakso M Acarbose treatment and the risk of cardiovascular disease and hypertension in patients with impaired glucose tolerance: the STOP-NIDDM trial. JAMA 2003;290:486-94 [[12876091](#)]

### Halimi, 2000:

Halimi S, Le Berre MA, Grang V Efficacy and safety of acarbose add-on therapy in the treatment of overweight patients with Type 2 diabetes inadequately controlled with metformin: a double-blind, placebo-controlled study. Diabetes Res Clin Pract 2000;50:49-56 [[10936668](#)]

### Rosenstock, 1998:

Rosenstock J, Brown A, Fischer J, Jain A, Littlejohn T, Nadeau D, Sussman A, Taylor T, Krol A, Magner J Efficacy and safety of acarbose in metformin-treated patients with type 2 diabetes. Diabetes Care 1998;21:2050-5 [[9839093](#)]

## 6 impaired fasting glucose

Trial	Treatments	Patients	Trials design and methods
error vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
<b>STOP-NIDDM (Chiasson) , 2002</b> n=714/715 follow-up: 3.3 years	acarbose 100mg three times daily versus placebo	patients with impaired glucose tolerance (WHO 1985 criteria)	Parallel groups double blind Canada, Germany, Austria, Nordic countries, Spain, Israel

More details and results :

- prevention for impaired fasting glucose in all type of patients at <http://www.trialresultscenter.org/go-Q342>

## References

### STOP-NIDDM (Chiasson), 2002:

Chiasson JL, Josse RG, Gomis R, Hanefeld M, Karasik A, Laakso M Acarbose for prevention of type 2 diabetes mellitus: the STOP-NIDDM randomised trial. *Lancet* 2002;359:2072-7 [[12086760](#)]

Chiasson JL, Josse RG, Gomis R, Hanefeld M, Karasik A, Laakso M Acarbose treatment and the risk of cardiovascular disease and hypertension in patients with impaired glucose tolerance: the STOP-NIDDM trial. *JAMA* 2003;290:486-94 [[12876091](#)]

## 7 thoracic aortic aneurysm

Trial	Treatments	Patients	Trials design and methods
<b>error vs error</b> <b>INSTEAD , 2009</b> [NCT00525356] n=72/68 follow-up: 2 y	thoracic endovascular repair (TEVAR) with a stent graft plus optimal medical therapy versus optimum medical management	patients with stable uncomplicated type-B aortic dissection (dissection of the descending aorta)	Parallel groups open

More details and results :

- endovascular treatment for thoracic aortic aneurysm in all type of patients at <http://www.trialresultscenter.org/go-Q367>

## References

### INSTEAD, 2009:

Nienaber CA, Rousseau H, Eggebrecht H, Kische S, Fattori R, Rehders TC, Kundt G, Scheinert D, Czerny M, Kleinfeldt T, Zipfel B, Labrousse L, Ince H Randomized Comparison of Strategies for Type B Aortic Dissection. The INvestigation of STent grafts in Aortic Dissection (INSTEAD) Trial. *Circulation* 2009;; [[19996018](#)]