Clinical trials of nifedipine

TrialResults-center

1   acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
nifedipine vs			
Muller , 1984 n=93/88 follow-up: 14 days	-	-	Parallel groups double blind
Gordon , 1984 n=13/13 follow-up: 1 day	-	-	Parallel groups single blind
MI study group , 1979 n=904/888	-	-	Parallel groups open
nifedipine vs placebo			
SPRINT II , 1993 n=682/676 follow-up: 6 months	Nifedipine 20mgx3 started within 3hr of hopsital admission for 6 months versus placebo	men and women with suspected acute MI	Parallel groups Double blind Israel
Sirnes , 1984 n=112/115 follow-up: 42 days	Nifedipine 5x10mg versus placebo	patients with suspected acute myocardial infarction	Parallel groups double blind
Gottlieb , 1988 n=64/68 follow-up: 42 days	Nifedipine 10 to 30mgx4 versus placebo	-	Parallel groups double blind
Eisenberg , 1985 n=25/25 follow-up: 12 days	Nifedipine 20mgx4 versus placebo	patients with nontransmural myocardial infarction	Parallel groups double blind
Bradagan , 1986 n=60/61 follow-up: 2 days	Nifedipine 10mgx4 versus placebo	patients with suspected acute myocardial infarction within 6hrs	Parallel groups double blind
Loogna , 1985 n=23/34 follow-up:	Nifedipine 4x10mg versus placebo	patients with acute myocardial infarction within 6 h from onset of symptoms	Parallel groups double blind

Trial	Treatments	Patients	Trials design and methods
TRENT (Wilcox) , 1986 n=2240/2251 follow-up: 28 days	Nifedipine 4x10mg versus placebo	patients with suspected myocardial infarction	Parallel groups double blind
Walker , 1988 n=217/217 follow-up:	Nifedipine 6x10mg for 48hrs versus placebo	patients with suspected myocardial infarction within six hours from the onset of chest pain	Parallel groups double blind
Jaffe , 1987 n=13/9 follow-up: 7 days	Nifedipine 6x20mg versus placebo	patients with acute myocardial infarction	Parallel groups single blind
Erbel , 1988 n=74/75 follow-up: hospital stay	Nifedipine 20mgx3 versus placebo	patients with acute myocardial infarction	Parallel groups double blind
SPRINT I , 1988 n=1130/1146 follow-up: 1 year	Nifedipine 10mgx3 versus placebo	patient surviving MI 7 and 21 days after admission	Parallel groups Double blind Israel

More details and results :

References

Muller, 1984:

Muller JE, Morrison J, Stone PH, Rude RE, Rosner B, Roberts R, Pearle DL, Turi ZG, Schneider JF, Serfas DH Nifedipine therapy for patients with threatened and acute myocardial infarction: a randomized, double-blind, placebo-controlled comparison Circulation 1984;69:740-7 [6365350]

Gordon, 1984:

Held PH, Yusuf S, Furberg CD Calcium channel blockers in acute myocardial infarction and unstable angina: an overview BMJ 1989;299:1187-92 [2513047]

MI study group, 1979:

Acta cardiol 1979;34(suppl24):7-46

SPRINT II, 1993:

Goldbourt U, Behar S, Reicher-Reiss H, Zion M, Mandelzweig L, Kaplinsky E Early administration of nifedipine in suspected acute myocardial infarction. The Secondary Prevention Reinfarction Israel Nifedipine Trial 2 Study Arch Intern Med 1993;153:345-53 [8285927]

Sirnes, 1984:

Sirnes PA, Overskeid K, Pedersen TR, Bathen J, Drivenes A, Frland GS, Kjekshus JK, Landmark K, Rokseth R, Sirnes KE Evolution of infarct size during the early use of nifedipine in patients with acute myocardial infarction: the Norwegian Nifedipine Multicenter Trial. Circulation 1984;70:638-44 [6383655]

Gottlieb, 1988:

Gottlieb SO, Becker LC, Weiss JL, Shapiro EP, Chandra NC, Flaherty JT, Gottlieb SH, Ouyang P, Mellits ED, Townsend SN Nifedipine in acute myocardial infarction: an assessment of left ventricular function, infarct size, and infarct expansion. A double blind, randomised, placebo controlled trial Br Heart J 1988;59:411-8 [3285878]

Eisenberg, 1985:

Eisenberg PR, Lee RG, Biello DR, Geltman EM, Jaffe AS Chest pain after nontransmural infarction: the absence of remediable coronary vasospasm. Am Heart J 1985;110:515-21 [3898794]

Bradagan, 1986:

Branagan JP, Walsh K, Kelly P, Collins WC, McCafferty D, Walsh MJ Effect of early treatment with nifedipine in suspected acute myocardial infarction. Eur Heart J 1986;7:859-65 [3792347]

Loogna, 1985:

Loogna E, Sylvn C, Groth T, Mogensen L Complexity of enzyme release during acute myocardial infarction in a controlled study with early nifedipine treatment. Eur Heart J 1985;6:114-9 [3891346]

TRENT (Wilcox), 1986:

Wilcox RG, Hampton JR, Banks DC, Birkhead JS, Brooksby IA, Burns-Cox CJ, Hayes MJ, Joy MD, Malcolm AD, Mather HG Trial of early nifedipine in acute myocardial infarction: the Trent study. Br Med J (Clin Res Ed) 1986;293:1204-8 [3096431]

Walker, 1988:

Walker LJ, MacKenzie G, Adgey AA Effect of nifedipine on enzymatically estimated infarct size in the early phase of acute myocardial infarction. Br Heart J 1988;59:403-10 [3285877]

Jaffe, 1987:

Jaffe AS, Biello DR, Sobel BE, Geltman EM Enhancement of metabolism of jeopardized myocardium by nifedipine Int J Cardiol 1987;15:77-89 [3553039]

Erbel, 1988:

Erbel R, Pop T, Meinertz T, Olshausen KV, Treese N, Henrichs KJ, Schuster CJ, Rupprecht HJ, Schlurmann W, Meyer J Combination of calcium channel blocker and thrombolytic therapy in acute myocardial infarction Am Heart J 1988;115:529-38 [3278574]

SPRINT I, 1988:

Secondary prevention reinfarction Israeli nifedipine trial (SPRINT). A randomized intervention trial of nifedipine in patients with acute myocardial infarction. The Israeli Sprint Study Group Eur Heart J 1988;9:354-64 [2898363]

Disegni E, Goldbourt U, Reicher-Reiss H, Kaplinsky E, Zion M, Boyko V, Behar S The predictive value of admission heart rate on mortality in patients with acute myocardial infarction. SPRINT Study Group. Secondary Prevention Reinfarction Israeli Nifedipine Trial J Clin Epidemiol 1995;48:1197-205 [7561981]

2   post myocardial infarction

Trial	Treatments	Patients	Trials design and methods
nifedipine vs			
MI study group , 1979 n=904/888	-	-	Parallel groups open
nifedipine vs placebo			
SPRINT II , 1993 n=682/676 follow-up: 6 months	Nifedipine 20mgx3 started within 3hr of hopsital admission for 6 months versus placebo	men and women with suspected acute MI	Parallel groups Double blind Israel
SPRINT I , 1988 n=1130/1146 follow-up: 1 year	Nifedipine 10mgx3 versus placebo	patient surviving MI 7 and 21 days after admission	Parallel groups Double blind Israel

More details and results :

- calcium channel blockers for post myocardial infarction in all type of patients at http://www.trialresultscenter.org/go-Q252

References

MI study group, 1979:

Acta cardiol 1979;34(suppl24):7-46

SPRINT II, 1993:

Goldbourt U, Behar S, Reicher-Reiss H, Zion M, Mandelzweig L, Kaplinsky E Early administration of nifedipine in suspected acute myocardial infarction. The Secondary Prevention Reinfarction Israel Nifedipine Trial 2 Study Arch Intern Med 1993;153:345-53 [8285927]

SPRINT I, 1988:

Secondary prevention reinfarction Israeli nifedipine trial (SPRINT). A randomized intervention trial of nifedipine in patients with acute myocardial infarction. The Israeli Sprint Study Group Eur Heart J 1988;9:354-64 [2898363]

Disegni E, Goldbourt U, Reicher-Reiss H, Kaplinsky E, Zion M, Boyko V, Behar S The predictive value of admission heart rate on mortality in patients with acute myocardial infarction. SPRINT Study Group. Secondary Prevention Reinfarction Israeli Nifedipine Trial J Clin Epidemiol 1995;48:1197-205 [7561981]

3   hypertension

Trial	Treatments	Patients	Trials design and methods
nifedipine vs atenolol+chlorthalidone			

Trial	Treatments	Patients	Trials design and methods
Castel , 1994 n=146/205 follow-up:	Nifedipine 20mg/d versus Clonidine 0.15mg/d (n=61) or atenolol 100mg/d + chlorthalidone 25mg/d	-	
nifedipine vs coamilozide			
INSIGHT (diabetic subgroup) , 2000 n=649/653 follow-up: 4 y	Nifedipine GITS 30 mg daily versus co-amilozide hydrochlorothiazide 25 mg plus amiloride 2.5 mg	diabetic (subgroup) patients aged 55-80 years with hypertension (blood pressure >= 150/95 mm Hg, or >= 160 mmHg systolic)	Parallel groups double-blind Europe, Israel
nifedipine vs hydrochlorothiazide+amiloride			
INSIGHT , 2000 n=3157/3164 follow-up: at least 3 years	nifedipine GITS 30mg/d versus hydrochlorothiazide 25mg/d + amiloride 2.5mg/d	HBP + RF	Parallel groups Double blind

More details and results :

- anti hypertensive agents for hypertension in elderly (60 years and more) at http://www.trialresultscenter.org/go-Q9

- anti hypertensive agents for hypertension in diabetic patients at http://www.trialresultscenter.org/go-Q10

- anti hypertensive agents for hypertension in all type of patient at http://www.trialresultscenter.org/go-Q13

- anti hypertensive agents for hypertension in patients with additional risk factor at http://www.trialresultscenter.org/go-Q686

References

Castel, 1994:

Casiglia E, Spolaore P, Mazza A, Ginocchio G, Colangeli G, Onesto C, Di Menza G, Pegoraro L, Ambrosio GB Effect of two different therapeutic approaches on total and cardiovascular mortality in a Cardiovascular Study in the Elderly (CASTEL). Jpn Heart J 1994;35:589-600 [7830324]

INSIGHT (diabetic subgroup), 2000:

Brown MJ, Palmer CR, Castaigne A, de Leeuw PW, Mancia G, Rosenthal T, Ruilope LM Morbidity and mortality in patients randomised to double-blind treatment with a long-acting calcium-channel blocker or diuretic in the International Nifedipine GITS study: Intervention as a Goal in Hypertension Treatment (INSIGHT). Lancet 2000;356:366-72 [10972368] 10.1016/S0140-6736(00)02527-7

Mancia G, Brown M, Castaigne A, de Leeuw P, Palmer CR, Rosenthal T, Wagener G, Ruilope LM Outcomes with nifedipine GITS or Co-amilozide in hypertensive diabetics and nondiabetics in Intervention as a Goal in Hypertension (INSIGHT). Hypertension 2003;41:431-6 [12623939] 10.1161/01.HYP.0000057420.27692.AD

INSIGHT, 2000:

Brown MJ, Palmer CR, Castaigne A, de Leeuw PW, Mancia G, Rosenthal T, Ruilope LM Morbidity and mortality in patients randomised to double-blind treatment with a long-acting calcium-channel blocker or diuretic in the International Nifedipine GITS study: Intervention as a Goal in Hypertension Treatment (INSIGHT). Lancet 2000 Jul 29;356:366-72 [10972368]

4 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
nifedipine vs metoprolol			
HINT (nifedipine vs metoprolol) , 1988 n=NA follow-up: ND	nifedipine versus metoprolol	patients with unstable angina not pretreated with a beta-blocker and of nifedipine	Parallel groups ND

More details and results :

- calcium channel blockers for acute coronary syndrome in all type of patients at http://www.trialresultscenter.org/go-Q222

References

HINT (nifedipine vs metoprolol), 1988:

Tijssen JG, Lubsen J Early treatment of unstable angina with nifedipine and metoprolol–the HINT trial. J Cardiovasc Pharmacol 1988;12 Suppl 1:S71-7 [2468838]

5 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
nifedipine vs placebo			
ACTION , 1998 n=565/545 follow-up: 4.9y	Nifedipine GITS versus placebo	patients aged at least 35 years with stable angina pectoris and proven coronary artery disease; subgroup of diabetic patients	Parallel groups double-blind 19 countries
nifedipine vs ACE inhibitor			
JMIC-B (diabetic subgroup) , 2004 n=199/173 follow-up: 3 years	nifedipine retard versus angiotensin converting enzyme inhibitors	outpatients aged under 75 years who had diagnoses of both hypertension and coronary artery disease	Parallel groups open Japan
nifedipine vs coamilozide			
INSIGHT (diabetic subgroup) , 2000 n=649/653 follow-up: 4 y	Nifedipine GITS 30 mg daily versus co-amilozide hydrochlorothiazide 25 mg plus amiloride 2.5 mg	diabetic (subgroup) patients aged 55-80 years with hypertension (blood pressure >= 150/95 mm Hg, or >= 160 mmHg systolic)	Parallel groups double-blind Europe, Israel

More details and results :

- anti hypertensive agents for diabetes type 2 in patients with hypertension at http://www.trialresultscenter.org/go-Q83

- anti hypertensive agents for diabetes type 2 in patients with or without hypertension at http://www.trialresultscenter.org/go-Q414

References

ACTION, 1998:

Danchin N, Wagener G, Kirwan B, De Brouwer S, Lubsen J, Poole-WilsonP. Efficacy and safety of long-acting nifedipine in patients with symptomatic stable angina pectoris with and without diabetes: the action trial. Doctoral thesis http://publishing.eur.nl/ir/repub/asset/10627/

Poole-Wilson PA, Lubsen J, Kirwan BA, van Dalen FJ, Wagener G, Danchin N, Just H, Fox KA, Pocock SJ, Clayton TC, Motro M, Parker JD, Bourassa MG, Dart AM, Hildebrandt P, Hjalmarson A, Kragten JA, Molhoek GP, Otterstad JE, Seabra-Gomes R, Soler-Soler J, We Effect of long-acting nifedipine on mortality and cardiovascular morbidity in patients with stable angina requiring treatment (ACTION trial): randomised controlled trial. Lancet 2004;364:849-57 [15351192] 10.1016/S0140-6736(04)16980-8

JMIC-B (diabetic subgroup), 2004:

Yui Y, Sumiyoshi T, Kodama K, Hirayama A, Nonogi H, Kanmatsuse K, Origasa H, Iimura O, Ishii M, Saruta T, Arakawa K, Hosoda S, Kawai C Comparison of nifedipine retard with angiotensin converting enzyme inhibitors in Japanese hypertensive patients with coronary artery disease: the Japan Multicenter Investigation for Cardiovascular Diseases-B (JMIC-B) randomized trial. Hypertens Res 2004;27:181-91 [15080377]

Yui Y, Sumiyoshi T, Kodama K, Hirayama A, Nonogi H, Kanmatsuse K, Origasa H, Iimura O, Ishii M, Saruta T, Arakawa K, Hosoda S, Kawai C Nifedipine retard was as effective as angiotensin converting enzyme inhibitors in preventing cardiac events in high-risk hypertensive patients with diabetes and coronary artery disease: the Japan Multicenter Investigation for Cardiovascular Diseases-B (JMIC-B) subgroup analysis. Hypertens Res 2004;27:449-56 [15302980]

INSIGHT (diabetic subgroup), 2000:

Brown MJ, Palmer CR, Castaigne A, de Leeuw PW, Mancia G, Rosenthal T, Ruilope LM Morbidity and mortality in patients randomised to double-blind treatment with a long-acting calcium-channel blocker or diuretic in the International Nifedipine GITS study: Intervention as a Goal in Hypertension Treatment (INSIGHT). Lancet 2000;356:366-72 [10972368] 10.1016/S0140-6736(00)02527-7

Mancia G, Brown M, Castaigne A, de Leeuw P, Palmer CR, Rosenthal T, Wagener G, Ruilope LM Outcomes with nifedipine GITS or Co-amilozide in hypertensive diabetics and nondiabetics in Intervention as a Goal in Hypertension (INSIGHT). Hypertension 2003;41:431-6 [12623939] 10.1161/01.HYP.0000057420.27692.AD

6   percutaneous coronary intervention

Trial	Treatments	Patients	Trials design and methods
nifedipine vs placebo			
Whitworth , 1986 n=100/98 follow-up: 6 months	nifedipine (10 mg qid) versus placebo	-	double blind

More details and results :

- restenosis prevention for percutaneous coronary intervention in all type of patients at http://www.trialresultscenter.org/go-Q318

References

Whitworth, 1986:

Whitworth HB, Roubin GS, Hollman J, Meier B, Leimgruber PP, Douglas JS Jr, King SB 3rd, Gruentzig AR Effect of nifedipine on recurrent stenosis after percutaneous transluminal coronary angioplasty. J Am Coll Cardiol 1986;8:1271-6 [2946740]

Entry terms: acebutolol, Sectral, Monitan, Rhotral, Neptal, atenolol, metoprolol, Metoprolol, Beloc-Duriles, Beloc Duriles, BelocDuriles, Betalok, Spesicor, Spesikor, H 93-26, H 93 26, H 9326, Lopressor, Metoprolol Tartrate, Seloken, Betaloc, Betaloc-Astra, Betaloc Astra, BetalocAstra, CGP-2175, CGP 2175, CGP2175, , Nifedipine, Adalat, Bay-1040, Bay 1040, Bay1040, BAY-a-1040, BAY a 1040, BAYa1040, Procardia XL, Nifedipine-GTIS, Nifedipine GTIS, Corinfar, Korinfar, Fenigidin, Nifangin, Nifedipine Monohydrochloride, Procardia, Vascard, Cordipin, Cordipine, , propranolol, nisoldipine, Bay K 5552,