

# Clinical trials of transmyocardial revascularization for coronary artery disease in all type of patients

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

## 1 transmyocardial revascularization

Trial	Treatments	Patients	Trials design and methods
<b>TMR+CABG vs CABG</b>			
<b>Allen , 2000</b> n=132/131 follow-up:	coronary bypass of suitable vessels plus transmyocardial revascularization to areas not graftable versus coronary bypass alone with nongraftable areas left unrevascularized	patients whose standard of care was coronary artery bypass grafting and who had one or more ischemic areas not amenable to bypass grafting	single blind
<b>Loubani , 2003</b> n=10/10 follow-up: 36 months	coronary artery bypass grafting plus transmyocardial laser revascularization with a holmium:YAG (yttrium-aluminum-garnet) laser to nongraftable areas versus coronary artery bypass grafting	Patients who had elective coronary artery bypass with one or more nongraftable coronary arteries	Parallel groups open UK
<b>Zhao , 2006</b> n=40/40 follow-up: 3.4y	transmyocardial laser revascularization (holmium: YAG) combined with off-pump coronary artery bypass versus off-pump coronary artery bypass	patients with diffusely diseased target vessels	Parallel groups open China
<b>TMR vs placebo</b>			
<b>Leon (high dose) , 2005</b> n=98/102 follow-up: 6 months	high-dose myocardial laser channels versus placebo (sham procedure)	patients with severe angina	Parallel groups double blind US
<b>Leon (low dose) , 2005</b> n=98/102 follow-up: 6 months	low-dose myocardial laser channels versus placebo (sham procedure)	patients with severe angina	Parallel groups double blind US
<b>TMR vs medical treatment</b>			
<b>Aaberge , 2000</b> n=50/50 follow-up: 12 months	transmyocardial revascularization with CO2-laser versus continued optimal medical treatment	patients with refractory angina not eligible for conventional revascularization	Parallel groups open Norway
<b>Allen , 1999</b> n=132/143 follow-up: 1 y	transmyocardial revascularization versus medical therapy alone	patients with medically refractory class IV angina and coronary disease that could not be treated with percutaneous or surgical revascularization	Parallel groups open US

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>ATLANTIC (Burkhoff) , 1999</b> n=92/90 follow-up: 1 y	Transmyocardial revascularisation versus medical treatment alone	patients with Canadian Cardiovascular Society Angina (CCSA) score III or IV, reversible ischaemia, and incomplete response to other therapies	Parallel groups open US
<b>Frazier , 1999</b> n=91/101 follow-up: 12 months (4y)	transmyocardial revascularization versus continued medical treatment	patients with end-stage coronary artery disease	Parallel groups open US
<b>Gray , 2003</b> n=36/37 follow-up: 12 months	percutaneous myocardial laser revascularization versus medical therapy alone	with stable angina pectoris (class III or IV) who were unsuitable for conventional revascularization and had evidence of reversible ischemia by thallium-201 scintigraphy, ejection fraction of $\geq 25\%$ , and myocardial wall thickness $\geq 8$ mm	Parallel groups open
<b>Huikeshoven , 2003</b> n=30 follow-up: 1y	XeCl excimer transmyocardial laser revascularization versus optimal cardiac medication	-	Parallel groups open
<b>March , 1999</b> n=198 follow-up: 12 months	Transmyocardial laser revascularization versus continued medical management	patients with symptomatic end-stage coronary artery disease	Parallel groups open
<b>PACIFIC , 2000</b> n=110/111 follow-up: 12 months	Percutaneous transmyocardial laser revascularisation versus medical treatment only	patients with reversible ischaemia of Canadian Cardiovascular Society angina class III or IV and incomplete response to other therapies	Parallel groups open US, UK
<b>Salem , 2004</b> n=40/42 follow-up: 12 months	percutaneous myocardial laser revascularization versus optimal medical therapy	patients with stable angina pectoris (class III or IV) not amenable to conventional revascularization and with evidence of reversible ischemia, ejection fraction $\geq 25\%$ , and myocardial wall thickness $\geq 8$ mm	Parallel groups double blind Norway
<b>Schofield , 1999</b> n=94/94 follow-up: 1 y	Transmyocardial laser revascularisation versus medical management alone	patients with refractory angina	Parallel groups open
<b>Stone , 2002</b> n=71/70 follow-up: 6 months	percutaneous transmyocardial revascularization versus maximal medical therapy	patients with class III or IV angina caused by one or more chronically occluded native coronary arteries in which a percutaneous coronary intervention had failed	Parallel groups single blind (patient) US
<b>van der Sloot , 2004</b> n=15/15 follow-up: 12 months	XeCl excimer transmyocardial laser revascularization versus maximal medication	patients with refractory angina	Parallel groups open the Netherlands
<b>TMR vs thoracic sympathectomy</b>			
<b>Galianes , 2004</b> n=10/10 follow-up: 42 months	Transmyocardial laser revascularization by holmium: yttrium aluminum garnet laser versus thoracic sympathectomy	patients with nonrevascularizable coronary arteries and intractable angina	Parallel groups open

## References

### Allen, 2000:

Allen KB, Dowling RD, DelRossi AJ, Realyvasques F, Lefrak EA, Pfeffer TA, Fudge TL, Mostovych M, Schuch D, Szentpetery S, Shaar CJ Transmyocardial laser revascularization combined with coronary artery bypass grafting: a multicenter, blinded, prospective, randomized, controlled trial. *J Thorac Cardiovasc Surg* 2000;119:540-9 [[10694615](#)]

### Loubani, 2003:

Loubani M, Chin D, Leverment JN, Galianes M Mid-term results of combined transmyocardial laser revascularization and coronary artery bypass. *Ann Thorac Surg* 2003;76:1163-6 [[14530005](#)]

### Zhao, 2006:

Zhao H, Wan F, Guo JX, Chen Y, Xie JY, Yang W, Zhang P [Chronic effects of transmyocardial laser revascularization combined with off-pump coronary artery by pass (OPCAB) compared with OPCAB alone in patients with ischemic heart disease: a prospective multicenter follow-up study] *Zhonghua Xin Xue Guan Bing Za Zhi* 2006;34:710-3 [[17081396](#)]

### Leon (high dose), 2005:

Leon MB, Kornowski R, Downey WE, Weisz G, Baim DS, Bonow RO, Hendel RC, Cohen DJ, Gervino E, Laham R, Lembo NJ, Moses JW, Kuntz RE A blinded, randomized, placebo-controlled trial of percutaneous laser myocardial revascularization to improve angina symptoms in patients with severe coronary disease. *J Am Coll Cardiol* 2005;46:1812-9 [[16286164](#)]

### Leon (low dose), 2005:

Leon MB, Kornowski R, Downey WE, Weisz G, Baim DS, Bonow RO, Hendel RC, Cohen DJ, Gervino E, Laham R, Lembo NJ, Moses JW, Kuntz RE A blinded, randomized, placebo-controlled trial of percutaneous laser myocardial revascularization to improve angina symptoms in patients with severe coronary disease. *J Am Coll Cardiol* 2005 Nov 15;46:1812-9 [[16286164](#)]

### Aaberge, 2000:

Aaberge L, Nordstrand K, Dragsund M, Saatvedt K, Endresen K, Golf S, Geiran O, Abdelnoor M, Forfang K Transmyocardial revascularization with CO<sub>2</sub> laser in patients with refractory angina pectoris. Clinical results from the Norwegian randomized trial. *J Am Coll Cardiol* 2000;35:1170-7 [[10758957](#)]

Aaberge L, Rootwelt K, Blomhoff S, Saatvedt K, Abdelnoor M, Forfang K Continued symptomatic improvement three to five years after transmyocardial revascularization with CO<sub>2</sub> laser: a late clinical follow-up of the Norwegian Randomized trial with transmyocardial revascularization. *J Am Coll Cardiol* 2002;39:1588-93 [[12020484](#)]

Aaberge L, Aakhus S, Nordstrand K, Abdelnoor M, Ihlen H, Forfang K Myocardial performance after transmyocardial revascularization with CO<sub>2</sub> laser. A dobutamine stress echocardiographic study. *Eur J Echocardiogr* 2001;2:187-96 [[11882452](#)]

Aaberge L, Rootwelt K, Smith HJ, Nordstrand K, Forfang K Effects of transmyocardial revascularization on myocardial perfusion and systolic function assessed by nuclear and magnetic resonance imaging methods. *Scand Cardiovasc J* 2001;35:8-13 [[11354578](#)]

### Allen, 1999:

Allen KB, Dowling RD, Fudge TL, Schoettle GP, Selinger SL, Gangahar DM, Angell WW, Petracek MR, Shaar CJ, O'Neill WW Comparison of transmyocardial revascularization with medical therapy in patients with refractory angina. *N Engl J Med* 1999;341:1029-36 [[10502592](#)]

Allen KB, Dowling RD, Angell WW, Gangahar DM, Fudge TL, Richenbacher W, Selinger SL, Petracek MR, Murphy D Transmyocardial revascularization: 5-year follow-up of a prospective, randomized multicenter trial. *Ann Thorac Surg* 2004;77:1228-34 [[15063241](#)]

Allen KB, Dowling RD, DelRossi AJ, Realyvasques F, Lefrak EA, Pfeffer TA, Fudge TL, Mostovych M, Schuch D, Szentpetery S, Shaar CJ Transmyocardial laser revascularization combined with coronary artery bypass grafting: a multicenter, blinded, prospective, randomized, controlled trial. *J Thorac Cardiovasc Surg* 2000;119:540-9 [[10694615](#)]

Allen KB, Dowling RD, Schuch DR, Pfeffer TA, Marra S, Lefrak EA, Fudge TL, Mostovych M, Szentpetery S, Saha SP, Murphy D, Dennis H Adjunctive transmyocardial revascularization: five-year follow-up of a prospective, randomized trial. *Ann Thorac Surg* 2004;78:458-65; discussion 458-65 [[15276496](#)]

### ATLANTIC (Burkhoff), 1999:

Burkhoff D, Schmidt S, Schulman SP, Myers J, Resar J, Becker LC, Weiss J, Jones JW Transmyocardial laser revascularisation compared with continued medical therapy for treatment of refractory angina pectoris: a prospective randomised trial. ATLANTIC Investigators. *Angina Treatments-Lasers and Normal Therapies in Comparison*. *Lancet* 1999;354:885-90 [[10489946](#)]

### Frazier, 1999:

Frazier OH, March RJ, Horvath KA Transmyocardial revascularization with a carbon dioxide laser in patients with end-stage coronary artery disease. *N Engl J Med* 1999;341:1021-8 [[10502591](#)]

Frazier OH, Tuzun E, Eichstadt H, Boyce SW, Lansing AM, March RJ, Sartori M, Kadipasaoglu KA Transmyocardial laser revascularization as an adjunct to coronary artery bypass grafting: a randomized, multicenter study with 4-year follow-up. *Tex Heart Inst J* 2004;31:231-9 [[15562842](#)]

Jones JW, Schmidt SE, Richman BW, Miller CC 3rd, Sapire KJ, Burkhoff D, Baldwin JC Holmium:YAG laser transmyocardial revascularization relieves angina and improves functional status. *Ann Thorac Surg* 1999;67:1596-601; discussion 1601-2 [[10391261](#)]

**Gray, 2003:**

Gray TJ, Burns SM, Clarke SC, Tait S, Sharples LD, Caine N, Schofield PM Percutaneous myocardial laser revascularization in patients with refractory angina pectoris. *Am J Cardiol* 2003;91:661-6 [[12633794](#)]

**Huikeshoven, 2003:**

Huikeshoven M, van der Sloot JA, Tukkie R, van Gemert MJ, Tijssen JG, Beek JF Improved quality of life after XeCl excimer transmyocardial laser revascularization: results of a randomized trial. *Lasers Surg Med* 2003;33:1-7 [[12866115](#)]

**March, 1999:**

March RJ Transmyocardial laser revascularization with the CO2 laser: one year results of a randomized, controlled trial. *Semin Thorac Cardiovasc Surg* 1999;11:12-8 [[9930706](#)]

**PACIFIC, 2000:**

Oesterle SN, Sanborn TA, Ali N, Resar J, Ramee SR, Heuser R, Dean L, Knopf W, Schofield P, Schaer GL, Reeder G, Masden R, Yeung AC, Burkhoff D Percutaneous transmyocardial laser revascularisation for severe angina: the PACIFIC randomised trial. *Potential Class Improvement From Intramyocardial Channels. Lancet* 2000;356:1705-10 [[11095257](#)]

**Salem, 2004:**

Salem M, Rotevatn S, Stavnes S, Brekke M, Vollset SE, Nordrehaug JE Usefulness and safety of percutaneous myocardial laser revascularization for refractory angina pectoris. *Am J Cardiol* 2004;93:1086-91 [[15110197](#)]

**Schofield, 1999:**

Schofield PM, Sharples LD, Caine N, Burns S, Tait S, Wistow T, Buxton M, Wallwork J Transmyocardial laser revascularisation in patients with refractory angina: a randomised controlled trial. *Lancet* 1999 Feb 13;353:519-24 [[10028979](#)]

Campbell HE, Tait S, Buxton MJ, Sharples LD, Caine N, Schofield PM, Wallwork J A UK trial-based cost-utility analysis of transmyocardial laser revascularization compared to continued medical therapy for treatment of refractory angina pectoris. *Eur J Cardiothorac Surg* 2001;20:312-8 [[11463549](#)]

**Stone, 2002:**

Stone GW, Teirstein PS, Rubenstein R, Schmidt D, Whitlow PL, Kosinski EJ, Mishkel G, Power JA A prospective, multicenter, randomized trial of percutaneous transmyocardial laser revascularization in patients with nonrecanalizable chronic total occlusions. *J Am Coll Cardiol* 2002;39:1581-7 [[12020483](#)]

**van der Sloot, 2004:**

van der Sloot JA, Huikeshoven M, Tukkie R, Verberne HJ, van der Meulen J, van Eck-Smit BL, van Gemert MJ, Tijssen JG, Beek JF Transmyocardial revascularization using an XeCl excimer laser: results of a randomized trial. *Ann Thorac Surg* 2004;78:875-81; discussion 881-2 [[15337012](#)]

**Galianes, 2004:**

Galianes M, Loubani M, Sensky PR, Hassouna A, Cherryman GR, Leverment JN, Samani NJ Efficacy of transmyocardial laser revascularization and thoracic sympathectomy for the treatment of refractory angina. *Ann Thorac Surg* 2004;78:122-8 [[15223416](#)]

## 2 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.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.