

Clinical trials of catheter ablation

TrialResults-center www.trialresultscenter.org

1 atrial fibrillation

Trial	Treatments	Patients	Trials design and methods
catheter ablation vs control			
Forleo , 2009 n=35/35 follow-up: 12 months	pulmonary vein isolation versus antiarrhythmic drug treatment	patients with diabetes mellitus type 2 and paroxysmal or persistent AF	Parallel groups open Italy
A4 (Jais) , 2008 [NCT00540787] n=53/59 follow-up: 12 months	catheter ablation versus antiarrhythmic drugs	patients with paroxysmal AF resistant to at least 1 antiarrhythmic drug.	Parallel groups open France,Canada, USA
ThermoCool AF , 2008 [NCT00116428] n=106/61 follow-up: 9 months	catheter ablation versus antiarrhythmic drug therapy with a class I or III drug	patients with AF who were nonresponsive to previous treatment with antiarrhythmic drugs	Parallel groups open
Oral , 2006 n=77/69 follow-up: 12 months	circumferential pulmonary-vein ablation and amiodarone versus amiodarone and two cardioversions during the first three months alone	patients with chronic atrial fibrillation	Parallel groups open Italy, USA
APAF (Pappone) , 2006 n=99/99 follow-up: 12 months	left atrial catheter ablation versus 65279;Flecainide acetate, propafenone hydrochloride, or sotalol hydrochloride	65279;Drug-refractory paroxysmal AF >=6mo	Parallel groups open Italy
CAFCOAF (Stabile) , 2006 n=68/69 follow-up: 12 months	left atrial catheter ablation plus amiodarone or other drugs versus Amiodarone or other drugs	Drug-refractory or drug-intolerant paroxysmal or persistent AF	Parallel groups open blinded assessment Italy
Lakkireddy , 2006 n=138/139 follow-up:	-	-	Parallel groups USA
Wazni , 2005 n=32/35 follow-up: 12 months	Pulmonary vein isolation versus Flecainide, propafenone, or sotalol; amiodarone if needed	Drug-naive monthly symptomatic AF >=3mo	Parallel groups open USA, Italy,Germany

continued...

Trial	Treatments	Patients	Trials design and methods
Krittayaphong , 2003 n=15/15 follow-up: 12 months	left atrial catheter ablation versus amiodarone	drug-refractory amiodarone-naive paroxysmal or persistent AF >=6mo	open Thailand
CABANA , 2018 <i>unpublished</i> [NCT00911508].] n=2204 follow-up:	left atrial catheter ablation versus current state-of-the-art therapy with either rate control or rhythm control drugs	patients with untreated or incompletely treated AF	Parallel groups open North America, Western and Eastern Europe, Asia, and Australia
STOP-AF , 2010 [NCT00523978] n=163/82 follow-up: 12 mo	cryo-balloon catheter for pulmonary vein isolation versus nonfailed antiarrhythmic drugs	patients with paroxysmal atrial fibrillation	Parallel groups open
MANTRA-PAF <i>ongoing</i> [NCT00133211] n=NA follow-up: 2 years	Radiofrequency Ablation versus Medical Antiarrhythmic Treatment	Paroxysmal Atrial Fibrillation	Parallel groups open
RESOLVE-AF <i>ongoing</i> [NCT00111488] n=200 follow-up:	Surgical Ablation with Microwave Energy versus control	patientst with permanent atrial fibrillation	Parallel groups open

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More details and results :

- catheter ablation for atrial fibrillation in all type of patients at <http://www.trialresultscenter.org/go-Q320>

References

Forleo, 2009:

Forleo GB, Mantica M, De Luca L, Leo R, Santini L, Panigada S, De Sanctis V, Pappalardo A, Laurenzi F, Avella A, Casella M, Dello Russo A, Romeo F, Pelargonio G, Tondo C Catheter ablation of atrial fibrillation in patients with diabetes mellitus type 2: results from a randomized study comparing pulmonary vein isolation versus antiarrhythmic drug therapy. *J Cardiovasc Electrophysiol* 2009;20:22-8 [18775050] [10.1111/j.1540-8167.2008.01275.x](https://doi.org/10.1111/j.1540-8167.2008.01275.x)

A4 (Jais), 2008:

Jas P, Cauchemez B, Macle L, Daoud E, Khairy P, Subbiah R, Hocini M, Extramiana F, Sacher F, Bordachar P, Klein G, Weerasooriya R, Clmenty J, Hassagerre M Catheter ablation versus antiarrhythmic drugs for atrial fibrillation: the A4 study. *Circulation* 2008 Dec 9;118:2498-505 [19029470]

ThermoCool AF, 2008:

Wilber DJ, Pappone C, Neuzil P, et al. *Circulation* 2008;118:2316 [abstract]

Wilber DJ, Pappone C, Neuzil P, De Paola A, Marchlinski F, Natale A, Macle L, Daoud EG, Calkins H, Hall B, Reddy V, Augello G, Reynolds MR, Vinekar C, Liu CY, Berry SM, Berry DA Comparison of antiarrhythmic drug therapy and radiofrequency catheter ablation in patients with paroxysmal atrial fibrillation: a randomized controlled trial. *JAMA* 2010;303:333-40 [20103757]

Oral, 2006:

Oral H, Pappone C, Chugh A, Good E, Bogun F, Pelosi F Jr, Bates ER, Lehmann MH, Vicedomini G, Augello G, Agricola E, Sala S, Santinelli V, Morady F. Circumferential pulmonary-vein ablation for chronic atrial fibrillation. *N Engl J Med* 2006;354:934-41 [[16510747](#)] [10.1056/NEJMoa050955](#)

APAF (Pappone), 2006:

Pappone C, Augello G, Sala S, Gugliotta F, Vicedomini G, Gulletta S, Paglino G, Mazzone P, Sora N, Greiss I, Santagostino A, LiVolsi L, Pappone N, Radinovic A, Manguso F, Santinelli V. A randomized trial of circumferential pulmonary vein ablation versus antiarrhythmic drug therapy in paroxysmal atrial fibrillation: the APAF Study. *J Am Coll Cardiol* 2006;48:2340-7 [[17161267](#)] [10.1016/j.jacc.2006.08.037](#)

CAFCOAF (Stabile), 2006:

Stabile G, Bertaglia E, Senatore G, De Simone A, Zoppo F, Donnici G, Turco P, Pascotto P, Fazzari M, Vitale DF. Catheter ablation treatment in patients with drug-refractory atrial fibrillation: a prospective, multi-centre, randomized, controlled study (Catheter Ablation For The Cure Of Atrial Fibrillation Study). *Eur Heart J* 2006;27:216-21 [[16214831](#)] [10.1093/eurheartj/ehi583](#)

Lakkireddy, 2006:

Lakkireddy DR, Patel D, Ryschon K, Thal S, Wazni O, Prasad S, et al. *J Am Coll Cardiol* 2006;47:17A.

Wazni , 2005:

Wazni OM, Marrouche NF, Martin DO, Verma A, Bhargava M, Saliba W, Bash D, Schweikert R, Brachmann J, Gunther J, Gutleben K, Pisano E, Potenza D, Fanelli R, Raviele A, Themistoclakis S, Rossillo A, Bonso A, Natale A. Radiofrequency ablation vs antiarrhythmic drugs as first-line treatment of symptomatic atrial fibrillation: a randomized trial. *JAMA* 2005;293:2634-40 [[15928285](#)]

Krittayaphong, 2003:

Krittayaphong R, Raungrattanaamporn O, Bhuripanyo K, Sriratanasathavorn C, Pooranawattanakul S, Punlee K, Kangkagate C. A randomized clinical trial of the efficacy of radiofrequency catheter ablation and amiodarone in the treatment of symptomatic atrial fibrillation. *J Med Assoc Thai* 2003;86 Suppl 1:S8-16 [[12866763](#)]

CABANA, 2018:

unpublished

STOP-AF, 2010:

Presented by Dr. Douglas Packer at the ACC.10/i2 Summit, Atlanta, GA, March 2010

Packer DL, Kowal RC, Wheelan KR, Irwin JM, Champagne J, Guerra PG, Dubuc M, Reddy V, Nelson L, Holcomb RG, Lehmann JW, Ruskin JN. Cryoballoon ablation of pulmonary veins for paroxysmal atrial fibrillation: first results of the North American Arctic Front (STOP AF) pivotal trial. *J Am Coll Cardiol* 2013;61:1713-23 [[23500312](#)]

MANTRA-PAF, :

ongoing trial NCT00133211

RESOLVE-AF, :

ongoing trial NCT00111488

2 ventricular tachycardia in patients with structural heart disease

Trial	Treatments	Patients	Trials design and methods
catheter ablation before ICD vs no ablation			
VTACH , 2009 [NCT00919373] n=54/56 follow-up: 27 mo	catheter ablation for ventricular tachycardia (VT) plus implantable cardioverter defibrillator versus implantable cardioverter defibrillator alone	Patients undergoing implantation of an ICD Patients undergoing implantation of an ICD	Parallel groups open Europe
SMASH-VT , 2007 [ISRCTN62488166] n=64/64 follow-up: 22.5 mo	defibrillator implantation with adjunctive catheter ablation versus defibrillator implantation alone	patients with a history of a myocardial infarction undergoing defibrillator implantation for spontaneous ventricular tachycardia or fibrillation	Parallel groups open

More details and results :

- catheter ablation of ventricular tachycardia for ventricular tachycardia in patients with structural heart disease in all type of patients at <http://www.trialresultscenter.org/go-Q382>

References

VTACH, 2009:

Kuck KH, Schaumann A, Eckardt L, Willems S, Ventura R, Delacrtaz E, Pitschner HF, Kautzner J, Schumacher B, Hansen PS Catheter ablation of stable ventricular tachycardia before defibrillator implantation in patients with coronary heart disease (VTACH): a multicentre randomised controlled trial. Lancet 2010 Jan 2;375:31-40 [20109864] [10.1016/S0140-6736\(09\)61755-4](https://doi.org/10.1016/S0140-6736(09)61755-4)

SMASH-VT, 2007:

Reddy VY, Reynolds MR, Neuzil P, Richardson AW, Taborsky M, Jongnarangsin K, Kralovec S, Sediva L, Ruskin JN, Josephson ME Prophylactic catheter ablation for the prevention of defibrillator therapy. N Engl J Med 2007;357:2657-65 [18160685]

3 patients with implantable cardioverter defibrillators

Trial	Treatments	Patients	Trials design and methods
catheter ablation before ICD vs no ablation			
VTACH , 2009 [NCT00919373] n=54/56 follow-up: 27 mo	catheter ablation for ventricular tachycardia (VT) plus implantable cardioverter defibrillator versus implantable cardioverter defibrillator alone	Patients undergoing implantation of an ICD Patients undergoing implantation of an ICD	Parallel groups open Europe

continued...

Trial	Treatments	Patients	Trials design and methods
SMASH-VT , 2007 [ISRCTN62488166] n=64/64 follow-up: 22.5 mo	defibrillator implantation with adjunctive catheter ablation versus defibrillator implantation alone	patients with a history of a myocardial infarction undergoing defibrillator implantation for spontaneous ventricular tachycardia or fibrillation	Parallel groups open

More details and results :

- catheter ablation for patients with implantable cardioverter defibrillators in all type of patients at <http://www.trialresultscenter.org/go-Q384>

References

VTACH, 2009:

Kuck KH, Schaumann A, Eckardt L, Willems S, Ventura R, Delacrtaz E, Pitschner HF, Kautzner J, Schumacher B, Hansen PS Catheter ablation of stable ventricular tachycardia before defibrillator implantation in patients with coronary heart disease (VTACH): a multicentre randomised controlled trial. Lancet 2010 Jan 2;375:31-40 [20109864] [10.1016/S0140-6736\(09\)61755-4](https://doi.org/10.1016/S0140-6736(09)61755-4)

SMASH-VT, 2007:

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