

# Clinical trials of Drug eluting stent for coronary artery disease in bifurcation lesion

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

## 1 double stenting

Trial	Treatments	Patients	Trials design and methods
<b>double stenting with PES vs single stenting</b>			
<b>BBC ONE , 2008</b> [NCT00351260] n=250/250 follow-up: 65279;9 months	systematically stenting of both vessels with drug eluting stents(culotte or crush techniques) and with mandatory kissing balloon dilatation versus stenting of the main vessel followed by optional kissing balloon dilatation/T-stent	patients with significant coronary bifurcation lesions	Parallel groups open
<b>double stenting with SES vs single stenting</b>			
<b>CACTUS , 2009</b> n=177/173 follow-up: 6 months	elective versus stenting of only the main branch, with provisional side-branch T-stenting	patients with true coronary bifurcation lesions	Parallel groups open Europe
<b>Colombo , 2004</b> n=43/43 follow-up: 6.4 months	stenting of both branches using sirolimus-eluting stent versus stenting of the main branch with provisional stenting of the side branch	patients with coronary bifurcation lesions	Parallel groups open Italy
<b>Ferenc , 2008</b> n=101/101 follow-up: 12 months	routine T-stenting with sirolimus-eluting stents in both branches versus provisional T-stenting with SES placement in the main branch followed by kissing-balloon angioplasty and provisional SES placement in the side branch only for inadequate results	patients with a coronary bifurcation lesion	Parallel groups open
<b>NORDIC , 2006</b> n=206/207 follow-up: 14 months	stenting with sirolimus-eluting stents of both main vessel and side branch versus stenting with sirolimus-eluting stent of main vessel and optional stenting of side branch	patients with a coronary bifurcation lesion	Parallel groups open
<b>Pan , 2004</b> n=44/47 follow-up: 11 months	Double stenting of both main and side branche versus single stenting of the main vessel only	patients with true coronary bifurcation lesions	Parallel groups open

## References

### BBC ONE, 2008:

Hildick-Smith D BBC ONE British Bifurcation Coronary study Presented at TCT, Washington, 2008

Hildick-Smith D, de Belder AJ, Cooter N, Curzen NP, Clayton TC, Oldroyd KG, Bennett L, Holmberg S, Cotton JM, Glennon PE, Thomas MR, Maccarthy PA, Baumbach A, Mulvihill NT, Henderson RA, Redwood SR, Starkey IR, Stables RH Randomized trial of simple versus complex drug-eluting stenting for bifurcation lesions: the British Bifurcation Coronary Study: old, new, and evolving strategies. *Circulation* 2010;121:1235-43 [20194880] [10.1161/CIRCULATIONAHA.109.888297](https://doi.org/10.1161/CIRCULATIONAHA.109.888297)

### CACTUS , 2009:

Colombo A, Bramucci E, Sacc S, Violini R, Lettieri C, Zanini R, Sheiban I, Paloscia L, Grube E, Schofer J, Bolognese L, Orlandi M, Niccoli G, Latib A, Airoldi F Randomized study of the crush technique versus provisional side-branch stenting in true coronary bifurcations: the CACTUS (Coronary Bifurcations: Application of the Crushing Technique Using Sirolimus-Eluting Stents) Study. *Circulation* 2009;119:71-8 [19103990] [10.1161/CIRCULATIONAHA.108.808402](https://doi.org/10.1161/CIRCULATIONAHA.108.808402)

### Colombo, 2004:

Colombo A, Moses JW, Morice MC, Ludwig J, Holmes DR Jr, Spanos V, Louvard Y, Desmedt B, Di Mario C, Leon MB Randomized study to evaluate sirolimus-eluting stents implanted at coronary bifurcation lesions. *Circulation* 2004;109:1244-9 [14981005] [10.1161/01.CIR.0000118474.71662.E3](https://doi.org/10.1161/01.CIR.0000118474.71662.E3)

### Ferenc, 2008:

Ferenc M, Gick M, Kienzle RP, Bestehorn HP, Werner KD, Comberg T, Kuebler P, Bttner HJ, Neumann FJ Randomized trial on routine vs. provisional T-stenting in the treatment of de novo coronary bifurcation lesions. *Eur Heart J* 2008;29:2859-67 [18845665] [10.1093/eurheartj/ehn455](https://doi.org/10.1093/eurheartj/ehn455)

### NORDIC , 2006:

Steigen TK, Maeng M, Wiseth R, Erglis A, Kumsars I, Narbute I, Gunnes P, Mannsverk J, Meyerdierks O, Rotevatn S, Niemel M, Kervinen K, Jensen JS, Galle A, Nikus K, Vikman S, Ravkilde J, James S, Aare J, Ylitalo A, Helqvist S, Sjgren I, Thayssen P, Vir Randomized study on simple versus complex stenting of coronary artery bifurcation lesions: the Nordic bifurcation study. *Circulation* 2006;114:1955-61 [17060387] [10.1161/CIRCULATIONAHA.106.664920](https://doi.org/10.1161/CIRCULATIONAHA.106.664920)

Jensen JS, Galle A, Lassen JF, Erglis A, Kumsars I, Steigen TK, Wiseth R, Narbute I, Gunnes P, Mannsverk J, Meyerdierks O, Rotevatn S, Niemel M, Kervinen K, Nikus K, Vikman S, Ravkilde J, James S, Aare J, Ylitalo A, Helqvist S, Sjgren I, Thayssen P, V Safety in simple versus complex stenting of coronary artery bifurcation lesions. The nordic bifurcation study 14-month follow-up results. *EuroIntervention* 2008;4:229-33 [19110788]

### Pan, 2004:

Pan M, de Lezo JS, Medina A, Romero M, Segura J, Pavlovic D, Delgado A, Ojeda S, Melin F, Herrador J, Urea I, Burgos L Rapamycin-eluting stents for the treatment of bifurcated coronary lesions: a randomized comparison of a simple versus complex strategy. *Am Heart J* 2004;148:857-64 [15523318] [10.1016/j.ahj.2004.05.029](https://doi.org/10.1016/j.ahj.2004.05.029)

## 2 drug-eluting stents

Trial	Treatments	Patients	Trials design and methods
<b>A vs B</b>			
<b>Nordic Bifurcation Study</b> <i>ongoing</i> [NCT00376571] n=NA follow-up:	Strategy of Routine Stenting Both Main Vessel and Side Branch versus Strategy of Routine Main Vessel Stenting and Optional Treatment of Side Branch	bifurcation lesions	
<b>crush stenting vs culotte stenting</b>			

continued...

Trial	Treatments	Patients	Trials design and methods
<b>Nordic Bifurcation Stent Technique Study</b> <i>ongoing</i> [NCT00292305] n=NA follow-up:	crush stenting versus culotte stenting	bifurcation lesions	
<b>kissing balloon vs no kissing balloon</b>			
<b>Nordic-Baltic Bifurcation Study III</b> , 2009 [NCT00914199] n=238/239 follow-up: 6 mo	Kissing balloon dilatation post-stenting of the main artery (one-stent technique) versus no kissing balloon dilatation	patients with bifurcation lesions	Parallel groups open Denmark, Finland, Latvia, Sweden, Norway

## References

**Nordic Bifurcation Study, 0:**

**Nordic Bifurcation Stent Technique Study, 0:**

**Nordic-Baltic Bifurcation Study III, 2009:**

Niemel M, Kervinen K, Erglis A, Holm NR, Maeng M, Christiansen EH, Kumsars I, Jegere S, Dombrovskis A, Gunnes P, Stavnes S, Steigen TK, Trovik T, Eskola M, Vikman S, Romppanen H, Mkiikallio T, Hansen KN, Thayssen P, Aberge L, Jensen LO, Hervold A, Airaks Randomized Comparison of Final Kissing Balloon Dilatation Versus No Final Kissing Balloon Dilatation in Patients With Coronary Bifurcation Lesions Treated With Main Vessel Stenting: The Nordic-Baltic Bifurcation Study III. *Circulation* 2011;123:79-86 [[21173348](https://doi.org/10.1161/CIRCULATIONAHA.110.966879)]  
[10.1161/CIRCULATIONAHA.110.966879](https://doi.org/10.1161/CIRCULATIONAHA.110.966879)

3

## 3 provisional T-stenting with drug-eluting stents

Trial	Treatments	Patients	Trials design and methods
<b>sirolimus eluting stent vs paclitaxel eluting stent</b>			
<b>Pan</b> , 2007 n=103/102 follow-up: 24 months (mean)	SES for provisional T-stenting versus PES for provisional T-stenting	patients with bifurcation lesions	Parallel groups open Spain

## References

**Pan, 2007:**

Pan M, Surez de Lezo J, Medina A, Romero M, Delgado A, Segura J, Ojeda S, Mazuelos F, Hernandez E, Melian F, Pavlovic D, Esteban F, Herrador J Drug-eluting stents for the treatment of bifurcation lesions: a randomized comparison between paclitaxel and sirolimus stents. *Am Heart J* 2007 Jan;153:15.e1-7 [[17174630](https://doi.org/10.1016/j.ahj.2006.11.001)]

## 4 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.