

Clinical trials of zotarolimus eluting stent

TrialResults-center www.trialresultscenter.org

1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
zotarolimus eluting stent vs paclitaxel eluting stent			
ZEST AMI (vs PES) , 2009 [NCT00422565] n=108/110 follow-up: 1 year (mean)	zotarolimus-eluting stent (Endeavor) versus paclitaxel-eluting stent (Taxus Libert)	Acute Myocardial Infarction Patients (STEMI)requiring primary angioplasty with symptom onset <= 12 hours	open Korea
zotarolimus eluting stent vs sirolimus eluting stent			
ZEST AMI (vs SES) , 2009 [NCT00422565] n=108/110 follow-up: 1 year (mean)	zotarolimus-eluting stent (Endeavor) versus sirolimus-eluting stents (Cypher)	Acute Myocardial Infarction Patients (STEMI)requiring primary angioplasty with symptom onset <= 12 hours	Parallel groups open Korea

└ More details and results :

- myocardial revascularization for acute myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q129>
- PCI for acute myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q246>

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2 stable angina

Trial	Treatments	Patients	Trials design and methods
zotarolimus eluting stent vs bare-metal stent			
ENDEAVOR II , 2006 n=598/599 follow-up: 12 months	AVE Zotarolimus-Eluting Driver versus Driver	single de novo native coronary artery stenosis	Parallel groups double-blind worldwide
zotarolimus eluting stent vs everolimus eluting stent			
RESOLUTE All comers , 2010 [NCT00617084.] n=1140/1152 follow-up: 12 months (5y)	zotarolimus-eluting stent versus everolimus-eluting stent (Xience)	adult patients with chronic, stable coronary artery disease or acute coronary syndromes, including myocardial infarction with or without ST-segment elevation	Parallel groups open
zotarolimus eluting stent vs paclitaxel eluting stent			
ENDEAVOR IV , 2009 <i>unpublished</i> [NCT00217269] n=773/775 follow-up: mean 36 mo	zotarolimus-eluting stent (Endeavor) versus paclitaxel-eluting stent (Taxus)	single de novo lesions in native coronary arteries with a reference vessel diameter of 2.5-3.5 mm	Parallel groups open US
ZoMaxx phase 2 ongoing [NCT00140101] n=NA follow-up:	ZoMaxx drug-eluting stent versus TAXUS Express2	de Novo Coronary Artery Lesions	
zotarolimus eluting stent vs sirolimus eluting stent			
ENDEAVOR III , 2006 [NCT00217256] n=327/109 follow-up: 12 months (and 24 months)	ABT-578 coated Endeavor versus Cypher	single de novo lesions in native coronary arteries 2.5-3.5 mm in diameter	Parallel groups open US
PROTECT , 2012 [NCT00476957] n=4357/4352 follow-up:	Medtronic Endeavor Zotarolimus Eluting Coronary Stent System versus Cordis Cypher Sirolimus-eluting Coronary Stent	unselected patients (patients 18 years or older who were undergoing stenting for elective, unplanned, or emergency procedures in native coronary arteries)	Parallel groups open-label
ZEST (vs SES) , 2009 [NCT00418067] n=883/878 follow-up: 1 year	zotarolimus-eluting stents versus sirolimus-eluting stents	Patients with coronary artery disease	Parallel groups Open Korea
DIABEDES IV ongoing [NCT00552994] n=NA follow-up:	Cypher select plus versus Xience V	diabetic patients	

continued...

Trial	Treatments	Patients	Trials design and methods
PRISON III , 2007 <i>ongoing</i> [NCT00428454] n=NA follow-up: 8 months	Endeavor versus Cypher	patients with total coronary occlusions for at least 2 weeks with evidence of ischemia related to the occluded coronary artery	Parallel groups open

More details and results :

- myocardial revascularization for stable angina in all type of patient at <http://www.trialresultscenter.org/go-Q25>

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ZoMaxx phase 2, 0:

ongoing trial NCT00140101

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ongoing trial NCT00428454

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3 coronary artery disease

Trial	Treatments	Patients	Trials design and methods
zotarolimus eluting stent vs bare-metal stent			
ENDEAVOR II , 2006 n=598/599 follow-up: 12 months	AVE Zotarolimus-Eluting Driver versus Driver	single de novo native coronary artery stenosis	Parallel groups double-blind worldwide
zotarolimus eluting stent vs everolimus eluting stent			
RESOLUTE All comers , 2010 [NCT00617084.] n=1140/1152 follow-up: 12 months (5y)	zotarolimus-eluting stent versus everolimus-eluting stent (Xience)	adult patients with chronic, stable coronary artery disease or acute coronary syndromes, including myocardial infarction with or without ST-segment elevation	Parallel groups open
TWENTE , 2012 [NCT01066650] n=NA follow-up: 1 year	zotarolimus-eluting stent versus everolimus-eluting stent	"real-world" patients	Parallel groups single (patient-blinded)
zotarolimus eluting stent vs paclitaxel eluting stent			
ENDEAVOR IV , 2009 <i>unpublished</i> [NCT00217269] n=773/775 follow-up: mean 36 mo	zotarolimus-eluting stent (Endeavor) versus paclitaxel-eluting stent (Taxus)	single de novo lesions in native coronary arteries with a reference vessel diameter of 2.5-3.5 mm	Parallel groups open US
ZEST (vs PES) , 2009 [NCT00418067] n=883/884 follow-up: 1 year	zotarolimus-eluting stents versus paclitaxel-eluting stents	Patients with coronary artery disease	NA
ZEST AMI (vs PES) , 2009 [NCT00422565] n=108/110 follow-up: 1 year (mean)	zotarolimus-eluting stent (Endeavor) versus paclitaxel-eluting stent (Taxus Libert)	Acute Myocardial Infarction Patients (STEMI) requiring primary angioplasty with symptom onset <= 12 hours	open Korea
ZoMaxx I , 2008 n=199/197 follow-up: 9 months	ZoMaxx zotarolimus-eluting stent versus Taxus paclitaxel-eluting stent	patients with single de novo coronary lesions and with lesion length 10-30 mm and reference vessel diameter 2.5-3.5 mm	Parallel groups open
ZoMaxx phase 2 <i>ongoing</i> [NCT00140101] n=NA follow-up:	ZoMaxx drug-eluting stent versus TAXUS Express2	de Novo Coronary Artery Lesions	

continued...

Trial	Treatments	Patients	Trials design and methods
zotarolimus eluting stent vs sirolimus eluting stent			
ENDEAVOR III , 2006 [NCT00217256] n=327/109 follow-up: 12 months (and 24 months)	ABT-578 coated Endeavor versus Cypher	single de novo lesions in native coronary arteries 2.5-3.5 mm in diameter	Parallel groups open US
PROTECT , 2012 [NCT00476957] n=4357/4352 follow-up:	Medtronic Endeavor Zotarolimus Eluting Coronary Stent System versus Cordis Cypher Sirolimus-eluting Coronary Stent	unselected patients (patients 18 years or older who were undergoing stenting for elective, unplanned, or emergency procedures in native coronary arteries)	Parallel groups open-label
SORT-OUT-3 , 2010 [NCT00660478] n=1162/1171 follow-up: 9 months (18 mo,3yrs)	Zotarolimus-eluting stents versus sirolimus-eluting stents (SES)	Patients With Coronary Artery Disease undergoing PCI for any indication	open
ZEST (vs SES) , 2009 [NCT00418067] n=883/878 follow-up: 1 year	zotarolimus-eluting stents versus sirolimus-eluting stents	Patients with coronary artery disease	Parallel groups Open Korea
ZEST AMI (vs SES) , 2009 [NCT00422565] n=108/110 follow-up: 1 year (mean)	zotarolimus-eluting stent (Endeavor) versus sirolimus-eluting stents (Cypher)	Acute Myocardial Infarction Patients (STEMI)requiring primary angioplasty with symptom onset <= 12 hours	Parallel groups open Korea
DIABEDES IV <i>ongoing</i> [NCT00552994] n=NA follow-up:	Cypher select plus versus Xience V	diabetic patients	
PRISON III , 2007 <i>ongoing</i> [NCT00428454] n=NA follow-up: 8 months	Endeavor versus Cypher	patients with total coronary occlusions for at least 2 weeks with evidence of ischemia related to the occluded coronary artery	Parallel groups open

More details and results :

- myocardial revascularization for coronary artery disease in all type of patient at <http://www.trialresultscenter.org/go-Q26>
- myocardial revascularization for coronary artery disease in diabetic patients at <http://www.trialresultscenter.org/go-Q30>
- Drug eluting stent for coronary artery disease in all type of patients at <http://www.trialresultscenter.org/go-Q206>
- Drug eluting stent for coronary artery disease in diabetic patients at <http://www.trialresultscenter.org/go-Q207>

- Drug eluting stent for coronary artery disease in acute myocardial infarction at <http://www.trialresultscenter.org/go-Q208>
- Drug eluting stent for coronary artery disease in unparticular patients at <http://www.trialresultscenter.org/go-Q215>
- Drug eluting stent for coronary artery disease in total occlusion at <http://www.trialresultscenter.org/go-Q216>

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ZoMaxx phase 2, 0:

ongoing trial NCT00140101

ENDEAVOR III, 2006:

Miyazawa A, Ako J, Hongo Y, Hur SH, Tsujino I, Courtney BK, Hassan AH, Kandzari DE, Honda Y, Fitzgerald PJ, , Comparison of vascular response to zotarolimus-eluting stent versus sirolimus-eluting stent: intravascular ultrasound results from ENDEAVOR III. *Am Heart J* 2008;155:108-13. [18082499] [10.1016/j.ahj.2007.08.008](https://doi.org/10.1016/j.ahj.2007.08.008)

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