# Clinical trials of DES

**TrialResults-center** www.trialresultscenter.org

## 1 stable angina

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **DES vs CABG** | | | |
| Boudriot , 2008<br>n=83/84<br>follow-up: 12 months | DES<br>versus<br>CABG | - | Parallel groups<br>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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## 2 hypertension

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **candesartan vs control** | | | |
| Takahashi , 2006<br>n=43/37<br>follow-up: 19.4 months | candesartan<br>versus<br>control | patients on chronic haemodialysis in stable condition and with no clinical evidence of cardiac disorders | Parallel groups<br>open |
| **candesartan vs conventional treatment** | | | |
| E-COST , 2005<br>n=1053/995<br>follow-up: | candesartan, 2 to 12 mg daily<br>versus<br>conventional antihypertensive drugs other than angiotensin converting enzyme inhibitors or ARBs | Japanese essential hypertensive subjects (sitting blood pressure 140-180/90-110 mmHg) aged 35-79 years | Parallel groups<br>single-blind<br>Japan |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| E-COST-R , 2005<br>n=69/72<br>follow-up: | candesartan<br>versus<br>conventional treatment | hypertensive subjects 60 to 75 years old with non-diabetic chronic renal insufficiency | Parallel groups<br>open |
| HIJ-CREATE , 2009<br>n=1024/1025<br>follow-up: 4.2 y (median) | angiotensin II receptor blocker-based therapy<br>versus<br>non-angiotensin II receptor blocker-based therapy | patients with angiographically documented coronary artery disease and hypertension | Parallel groups<br>open<br>Japan |
| **candesartan vs placebo** | | | |
| TROPHY , 2006<br>[NCT00227318]<br>n=409/400<br>follow-up: 4y | candesartan during 2y followed by 2y of placebo<br>versus<br>placebo | subjects with repeated measurements of systolic pressure of 130 to 139 mm Hg and diastolic pressure of 89 mm Hg or lower, or systolic pressure of 139 mm Hg or lower and diastolic pressure of 85 to 89 mm Hg | Parallel groups<br>double-blind<br>USA |
| SCOPE , 2003<br>n=2477/2460<br>follow-up: 3.7 y (mean) | candesartan, 816 mg once daily (target 160/90)<br>versus<br>placebo | patients aged 7089 years, with systolic blood pressure 160 179 mmHg, and/or diastolic blood pressure 9099 mmHg, and a Mini Mental State Examination (MMSE) test score >24 | Parallel groups<br>double-blind<br>15 countries |
| **deserpidine +methylclothiazide vs placebo** | | | |
| HSCS , 1974<br>n=233/219<br>follow-up: 2.3y | deserpidine 1mg/d + methylclothiazide 10mg/d<br>versus<br>placebo | stroke | Parallel groups<br>Double blind<br>USA |
| **Candesartan vs usual care** | | | |
| HIJ-CREATE , 2009<br>n=1025/1024<br>follow-up: up to 60 months | cardesartan adjusted dose for target arterial pressure of <130/85 mmHg<br>versus<br>usual care (non-ARB-based pharmacotherapy including angiotensin-converting enzyme-inhibitors) | hypertension with angiographically documented coronary artery disease (acute or stable) | Parallel groups<br>open<br>japan |
| Takahashi et al , 2006<br>n=43/37<br>follow-up: | Candesartan 4-8mg/day<br>versus<br>Conventional treatment | chronic haemodialysis patients | open |
| Suzuki et al , 2008<br>n=180/180<br>follow-up: 1-5 years | Candesartan 12 mg/day, losartan 100 mg/day, or valsartan 160 mg/day<br>versus<br>Conventional treatment | patients undergoing hemodialysis | open |
| **candesartan vs amlodipine** | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| CASE-J , 2008<br>n=2354/2349<br>follow-up: 3.2 years | candesartan-based regimen<br>versus<br>amlodipine-based regimen | high-risk Japanese hypertensive patients | Parallel groups<br>open (blinded assessment)<br>Japan |
| **candesartan vs hydrochlorothiazide** | | | |
| ALPINE , 2003<br>n=197/196<br>follow-up: 1 year | candesartan<br>versus<br>hydrochlorothiazide | newly detected hypertensives | Parallel groups<br>double-blind<br>Sweden |

More details and results :

- anti hypertensive agents for hypertension in all type of patient at http://www.trialresultscenter.org/go-Q13
- anti hypertensive agents for hypertension in nephropathy at http://www.trialresultscenter.org/go-Q19
- anti hypertensive agents for hypertension in post stroke at http://www.trialresultscenter.org/go-Q20
- angiotensin-receptor blockers for hypertension in all diseases requiring ACEi (HF, CHD, HT,...) at http://www.trialresultscenter.org/go-Q125
- anti hypertensive agents for hypertension in patients undergoing dialysis at http://www.trialresultscenter.org/go-Q281
- anti hypertensive agents for hypertension in subjects with pre-hypertension at http://www.trialresultscenter.org/go-Q404
- anti hypertensive agents for hypertension in uncomplicated hypertension at http://www.trialresultscenter.org/go-Q685
- anti hypertensive agents for hypertension in patients with additional risk factor at http://www.trialresultscenter.org/go-Q686
- anti hypertensive agents for hypertension in patients with cardiovascular disease at http://www.trialresultscenter.org/go-Q687

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# 3 heart failure

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **candesartan vs placebo** | | | |
| ARCH-J , 2003<br>n=148/144<br>follow-up: 155 d | Candesartan, 8 mg daily<br>versus<br>Placebo | patients with chronic heart failure who were not receiving ACE inhibitor therapy | Parallel groups<br>double blind |
| CHARM-Alternative , 2003<br>n=1013/1015<br>follow-up: Median, 33.7 mo | candesartan (target dose32 mg once daily)<br>versus<br>Placebo | patients with symptomatic heart failure and left-ventricular ejection fraction 40% or less who were notreceiving ACE inhibitors because of previous intolerance | Parallel groups<br>double blind<br>26 countries |
| CHARM preserved , 2003<br>n=1514/1509<br>follow-up: 36.6 months | candesartan target dose 32 mg once daily<br>versus<br>placebo | patients with NYHA II-IV heart failure and LVEF higher than 40% | Parallel groups<br>double blind<br>26 countries |
| Mitrovic et al. , 2003<br>n=174/44<br>follow-up: 12 wk | Candesartan, 2 mg, 4mg, 8mg, 16mg daily<br>versus<br>Placebo | patients with CHF (New York Heart Association class II or III) with impaired left ventricular function (ejection fraction <=40% ) and pulmonary capillary wedge pressure >=13 mm Hg | Parallel groups<br>double blind<br>Europe, South Africa |
| SPICE , 2000<br>n=179/91<br>follow-up: 12 wk | Candesartan, 16 mg daily<br>versus<br>Placebo | patients with chronic heart failure and left ventricular ejection fraction less than 35% , and history of discontinuing an ACE inhibitor because of intolerance | Parallel groups<br>double blind |
| STRETCH , 1999<br>n=633/211<br>follow-up: 12 wk | Candesartan, 4 mg, 8mg, 16mg daily<br>versus<br>Placebo | Male and female patients 21 to 80 years of age with mild to moderate symptomatic CHF (NYHA class II or III) | Parallel groups<br>Double blind<br>Germany, Czech Republic, Slovenia. |
| **candesartan+ACE inhibitor vs ACE inhibitor only** | | | |
| RESOLVD association , 1999<br>n=332/109<br>follow-up: 43 wk | Candesartan, 4 mg, 8mg daily, plus enalapril, 10 mg twice daily<br>versus<br>Enalapril, 10 mg twice daily | Patients with New York Heart Association functional class NYHA II, III, or IV CHF, 6-minute walk distance (6MWD) >500 m, and ejection fraction (EF) <0.40 | Parallel groups<br>multicenter |
| CHARM-Added , 2003<br>n=1276/1272<br>follow-up: Median, 41 mo | Candesartantarget dose 32 mg once daily<br>versus<br>Placebo | patients with New York Heart Association functional class IIIV CHF and left-ventricular ejection fraction40% or lower, and who were being treated with ACE inhibitors. | Parallel groups<br>double blind<br>26 countries |
| **candesartan vs enalapril** | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| RESOLVD (candesartan alone) , 1999<br>n=327/109<br>follow-up: 43 wk | Candesartan, 4 mg, 8mg, 16mg daily<br>versus<br>Enalapril, 10 mg twice daily | Patients with New York Heart Association functional class NYHA II, III, or IV CHF, 6-minute walk distance (6MWD) >500 m, and ejection fraction (EF) <0.40 | Parallel groups<br>Double blind<br>US, Canada, Europe, Brazil |

More details and results :

- angiotensin-receptor blockers for heart failure in all type of patients at http://www.trialresultscenter.org/go-Q65
- angiotensin-receptor blockers for heart failure in patients intolerant to ACE inhibitors at http://www.trialresultscenter.org/go-Q66
- angiotensin-receptor blockers for heart failure in patients previously untreated with ACE inhibitors at http://www.trialresultscenter.org/go-Q67
- angiotensin-receptor blockers for heart failure in patients already receiving ACE inhibitor at http://www.trialresultscenter.org/go-Q68
- angiotensin-receptor blockers for heart failure in patients with preserved-LVEF heart failure at http://www.trialresultscenter.org/go-Q233
- inhibition of the renin-angiotensin system (ACEI or ARB) for heart failure in patients with preserved-LVEF heart failure at http://www.trialresultscenter.org/go-Q234



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# 4 miscellaneous

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **candesartan vs control** | | | |
| Takahashi , 2006<br>n=43/37<br>follow-up: 19.4 months | candesartan<br>versus<br>control | patients on chronic haemodialysis in stable condition and with no clinical evidence of cardiac disorders | Parallel groups<br>open |
| **candesartan vs conventional treatment** | | | |
| E-COST , 2005<br>n=1053/995<br>follow-up: | candesartan, 2 to 12 mg daily<br>versus<br>conventional antihypertensive drugs other than angiotensin converting enzyme inhibitors or ARBs | Japanese essential hypertensive subjects (sitting blood pressure 140-180/90-110 mmHg) aged 35-79 years | Parallel groups<br>single-blind<br>Japan |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| E-COST-R , 2005<br>n=69/72<br>follow-up: | candesartan<br>versus<br>conventional treatment | hypertensive subjects 60 to 75 years old with non-diabetic chronic renal insufficiency | Parallel groups<br>open |
| HIJ-CREATE , 2009<br>n=1024/1025<br>follow-up: 4.2 y (median) | angiotensin II receptor blocker-based therapy<br>versus<br>non-angiotensin II receptor blocker-based therapy | patients with angiographically documented coronary artery disease and hypertension | Parallel groups<br>open<br>Japan |
| **candesartan vs placebo** | | | |
| TROPHY , 2006<br>[NCT00227318]<br>n=409/400<br>follow-up: 4y | candesartan during 2y followed by 2y of placebo<br>versus<br>placebo | subjects with repeated measurements of systolic pressure of 130 to 139 mm Hg and diastolic pressure of 89 mm Hg or lower, or systolic pressure of 139 mm Hg or lower and diastolic pressure of 85 to 89 mm Hg | Parallel groups<br>double-blind<br>USA |
| SCOPE , 2003<br>n=2477/2460<br>follow-up: 3.7 y (mean) | candesartan, 816 mg once daily (target 160/90)<br>versus<br>placebo | patients aged 7089 years, with systolic blood pressure 160 179 mmHg, and/or diastolic blood pressure 9099 mmHg, and a Mini Mental State Examination (MMSE) test score >24 | Parallel groups<br>double-blind<br>15 countries |
| **candesartan vs amlodipine** | | | |
| CASE-J , 2008<br>n=2354/2349<br>follow-up: 3.2 years | candesartan-based regimen<br>versus<br>amlodipine-based regimen | high-risk Japanese hypertensive patients | Parallel groups<br>open (blinded assessment)<br>Japan |
| **candesartan vs hydrochlorothiazide** | | | |
| ALPINE , 2003<br>n=197/196<br>follow-up: 1 year | candesartan<br>versus<br>hydrochlorothiazide | newly detected hypertensives | Parallel groups<br>double-blind<br>Sweden |



More details and results :

- angiotensin-receptor blockers for miscellaneous in all type of patients at http://www.trialresultscenter.org/go-Q425

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# 5 atrial fibrillation

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **candesartan vs placebo** | | | |
| CAPRAF (Tveit) , 2007<br>[NCT00130975]<br>n=86/85<br>follow-up: 6 months | candesartan 8 mg once daily for 3-6 weeks before and candesartan 16 mg once daily for 6 months after electrical cardioversion<br>versus<br>placebo | patients undergoing electrical cardioversion for persistent AF | Parallel groups<br>double blind |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| CHARM (AF ancillary study) , 2005<br>n=3225/3221<br>follow-up: 3.17 y | candesartan<br>versus<br>placebo | Heart failure | |

More details and results :

- prevention for atrial fibrillation in patient with history of atrial fibrillation at http://www.trialresultscenter.org/go-Q328
- prevention for atrial fibrillation in patients without history of AF (primary prevention) at http://www.trialresultscenter.org/go-Q331

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## 6 thrombosis prevention

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **desirudin vs enoxaparin** | | | |
| Ericksson , 1997<br>n=NA<br>follow-up: | desirudin 15mg SC twice daily for 8-12 days<br>versus<br>enoxaparin 40mg once daily for 8-12 days | Patients who undergo total hip replacement | Parallel groups<br>double blind<br>Europe |
| **desirudin vs UFH** | | | |
| REVASC , 1997<br>n=225/220<br>follow-up: | desirudin 15mg twice daily<br>versus<br>unfractionated heparin 5000 IU three times a day | patients having a primary elective total hip replacement | Parallel groups |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| Eriksson , 1996<br>n=1119<br>follow-up: | recombinant hirudin, desirudin (CGP 39393) 10, 15, or 20 mg twice daily started just before surgery and continued for 8-11 days<br>versus<br>unfractionated heparin 5000 IU three times daily started just before surgery and continued for 8-11 days | patients undergoing elective hip surgery | Parallel groups<br>double blind<br>Europe |

More details and results :

- antithrombotics for thrombosis prevention in orthopedic surgery at http://www.trialresultscenter.org/go-Q37
- antithrombotics for thrombosis prevention in elective hip replacement at http://www.trialresultscenter.org/go-Q39

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# 7 diabetes type 2

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **candesartan vs control** | | | |
| SCOPE (diabetic subgroup) , 2003<br>n=313/284<br>follow-up: 3.7 years | candesartan<br>versus<br>control | sub group of diabetic patients aged 70-89 years, with systolic blood pressure 160-179 mmHg, and/or diastolic blood pressure 90-99 mmHg, and a Mini Mental State Examination (MMSE) test score >or= 24 | Parallel groups<br>double-blind<br>15 countries |

More details and results :

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

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## 8 coronary artery disease

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **DES vs bare-metal stent** | | | |
| ISAR-CABG , 2011<br>[NCT00611910]<br>n=303/307<br>follow-up: 12 montsh (35 mo) | Drug-eluting stent (paclitaxel-eluting, sirolimus-eluting, or bioabsorbable polymer sirolimus-eluting stent)<br>versus<br>bare metal stent | patients with Bypass Graft Lesions | Parallel groups<br>open |
| **DES vs CABG** | | | |
| Boudriot , 2008<br>n=83/84<br>follow-up: 12 months | DES<br>versus<br>CABG | - | Parallel groups<br>open |
| SYNTAX (unprotected left main sub group) , 2009<br>n=312/302<br>follow-up: 12 months | PCI<br>versus<br>CABG | patients with left main coronary artery disease | Parallel groups<br>open |

More details and results :

- myocardial revascularization for coronary artery disease in all type of patient at http://www.trialresultscenter.org/go-Q26
- 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 bypass graft lesion at http://www.trialresultscenter.org/go-Q210
- Drug eluting stent for coronary artery disease in unprotected left main artery stenosis at http://www.trialresultscenter.org/go-Q212

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# 9 patients at high risk for cardiovascular events

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **candesartan vs placebo** | | | |
| SCOPE , 2003<br>n=2477/2460<br>follow-up: 3.7 y (mean) | candesartan, 816 mg once daily (target 160/90)<br>versus<br>placebo | patients aged 7089 years, with systolic blood pressure 160 179 mmHg, and/or diastolic blood pressure 9099 mmHg, and a Mini Mental State Examination (MMSE) test score >24 | Parallel groups<br>double-blind<br>15 countries |

More details and results :

- angiotensin-receptor blockers for patients at high risk for cardiovascular events in all type of patients at http://www.trialresultscenter.org/go-Q97

## References


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# 10 pulmonary embolism

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **desmoteplase vs alteplase** | | | |
| Tebbe , 2009<br>n=34<br>follow-up: | 125, 180, and 250 microg/kg bodyweight desmoteplase<br>versus<br>100 mg alteplase | acute massive pulmonary thromboembolism | Parallel groups<br>NA |

More details and results :

- fibrinolysis for pulmonary embolism in all type of patients at http://www.trialresultscenter.org/go-Q110

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# 11 superficial thrombophlebitis

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **desmin 200 vs desmin 100** | | | |
| Andreozzi (200 vs 100) , 1996<br>n=NA<br>follow-up: | Dermatan sulfate (Desmin) (100 mg twice s.c.)y8<br>versus<br>Desmin (100 mg once daily s.c.) | Patients with ST or varicophlebitis of the lower limbs | |
| **desmin SC vs desmin 100** | | | |
| Andreozzi (desmin SC vs 100) , 1996<br>n=NA | - | - | |

More details and results :

- antithrombotics for superficial thrombophlebitis in superficial thrombophlebitis of the leg at http://www.trialresultscenter.org/go-Q218

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**Andreozzi (desmin SC vs 100), 1996:**

# 12 heart failure with preserved LVEF

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **candesartan vs placebo** | | | |
| CHARM preserved , 2003<br>n=1514/1509<br>follow-up: 36.6 months | candesartan target dose 32 mg once daily<br>versus<br>placebo | patients with NYHA II-IV heart failure<br>and LVEF higher than 40% | Parallel groups<br>double blind<br>26 countries |

More details and results :

- All mechanism for heart failure with preserved LVEF in all type of patients at http://www.trialresultscenter.org/go-Q237

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