

# Clinical trials of angiotensin-receptor blockers for heart failure in all type of patients

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## 1 angiotensin receptor blocker

Trial	Treatments	Patients	Trials design and methods
<b>losartan vs losartan</b>			
<b>NCT00090259</b> <i>ongoing</i> [NCT00090259] n=3656 follow-up:	Losartan versus Losartan	Patients With Symptomatic Heart Failure Intolerant of ACE Inhibitor	Parallel groups double blind
<b>losartan 150mg vs losartan 50mg</b>			
<b>HEAAL , 2009</b> [NCT00090259] n=1921/1913 follow-up: 4.7 y (median)	losartan 150mg daily versus losartan 50 mg daily	patients with systolic heart failure who couldn't tolerate ACE inhibitors	Parallel groups double blind 30 countries
<b>valsartan vs no valsartan</b>			
<b>VALIDD , 2007</b> [NCT00170924] n=186/198 follow-up: 38 weeks	valsartan titrated up to 320 mg once daily versus placebo	Patients with hypertension and evidence of diastolic dysfunction	Parallel groups double blind USA, canada
<b>candesartan vs placebo</b>			
<b>ARCH-J , 2003</b> n=148/144 follow-up: 155 d	Candesartan, 8 mg daily versus Placebo	patients with chronic heart failure who were not receiving ACE inhibitor therapy	Parallel groups double blind
<b>CHARM-Alternative , 2003</b> n=1013/1015 follow-up: Median, 33.7 mo	candesartan (target dose 32 mg once daily) versus Placebo	patients with symptomatic heart failure and left-ventricular ejection fraction 40% or less who were not receiving ACE inhibitors because of previous intolerance	Parallel groups double blind 26 countries
<b>Mitrovic et al. , 2003</b> n=174/44 follow-up: 12 wk	Candesartan, 2 mg, 4mg, 8mg, 16mg daily versus Placebo	patients with CHF (New York Heart Association class II or III) with impaired left ventricular function (ejection fraction $\leq$ 40% ) and pulmonary capillary wedge pressure $\geq$ 13 mm Hg	Parallel groups double blind Europe, South Africa
<b>SPICE , 2000</b> n=179/91 follow-up: 12 wk	Candesartan, 16 mg daily versus 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 double blind
<b>STRETCH , 1999</b> n=633/211 follow-up: 12 wk	Candesartan, 4 mg, 8mg, 16mg daily versus Placebo	Male and female patients 21 to 80 years of age with mild to moderate symptomatic CHF (NYHA class II or III)	Parallel groups Double blind Germany, Czech Republic, Slovenia.

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>losartan vs placebo</b>			
<b>Losartan Phase III U.S. , 1995</b> <i>unpublished</i> n=237/114 follow-up: 12 wk	Losartan, 50 mg daily versus Placebo	patients with heart failure who had never received ACE inhibitors or who had discontinued ACE inhibitors	Parallel groups double blind
<b>Losartan Phase III International , 1996</b> <i>unpublished</i> n=254/131 follow-up: 12 wk	Losartan, 50 mg daily versus Placebo	patients with heart failure who had never received ACE inhibitors or who had discontinued ACE inhibitors	Parallel groups double blind
<b>valsartan vs placebo</b>			
<b>Mazayev et al. (vs placebo) , 1998</b> n=75/26 follow-up: 4 wk	valsartan 40, 80 or 160 mg twice daily versus Placebo	patients with chronic heart failure previously untreated with ACE inhibitors	Parallel groups Double blind Russia
<b>losartan vs captopril</b>			
<b>ELITE , 1997</b> n=352/370 follow-up: 48 wk	Losartan titrated to 50 mg once daily versus Captopril,titratedto 50 mg three times daily	ACE inhibitor naive patients (aged 65 years or more) with New York Heart Association (NYHA) class IIIIV heart failure and ejection fractions of 40% or less	Parallel groups Double blind United States, Europe and South America
<b>ELITE II , 2000</b> n=1578/1574 follow-up: median 1.5y	Losartan, target dose 50 mg daily versus Captopril, target dose 50 mg 3 times daily	patients aged 60 years or older with New York Heart Association class IIIIV heart failure and ejection fraction of 40% or less.	Parallel groups Double blind 46 countries
<b>candesartan vs enalapril</b>			
<b>RESOLVD (candesartan alone) , 1999</b> n=327/109 follow-up: 43 wk	Candesartan, 4 mg, 8mg, 16mg daily versus 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 Double blind US, Canada, Europe, Brazil
<b>losartan vs enalapril</b>			
<b>Losartan phase II S , 1996</b> n=108/58 follow-up: 8 weeks	losartan 50 or 25 mg/d versus enalapril 10mg twice daily	patient with heart failure	Parallel groups double blind
<b>losartan phase II US , 1996</b> n=78/38 follow-up: 12 weeks	losartan 25 and 50 mg/d versus enalapril 10mg twice daily	patients with heart failure	Parallel groups double blind
<b>Dickstein et al. , 1995</b> n=108/58 follow-up: 8 wk	Losartan, 25 mg, 50mg daily versus Enalapril, 10 mg twice daily	patients with moderate or severe chronic heart failure in New York Heart Association functional class III or IV and an ejection fraction <or = 35%	Parallel groups double blind

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
Lang et al. , 1997 n=78/38 follow-up: 12 wk	Losartan titrated to 25 mg ou 50 mg daily versus Enalapril, titrated to 10 mg twice daily	patients with congestive heart failure (New York Heart Association functionalclasses II to IV) and left ventricular ejection fraction <= 45% previously treated with stable doses of ACE inhibitors and diureticagents, with or without concurrent digitalis and othervasodilators	Parallel groups Double blind US, Canada
<b>telmisartan vs enalapril</b>			
REPLACE , 2001 n=301/77 follow-up: 12 wk	Telmisartan, 10 mg, 20mg, 40mg, 80mg daily versus Enalapril, 10 mg twice daily	ambulatory patients at least 21 years of age, in sinus rhythm, with chronic moderatesymptomatic heart failure (New York Heart Associationality.tion class IIIII) and a left ventricular ejection fraction of 40% or lower	Parallel groups Double blind
<b>valsartan vs enalapril</b>			
HEAVEN , 2002 n=70/71 follow-up: 12 wk	Valsartan, 160 mg daily versus Enalapril, 10 mg twice daily	Men and women with mild/moderate heart failure stabilised on an angiotensin-converting enzyme inhibitor and left ventricular ejection fraction 0.45 or less	Parallel groups Double blind
<b>valsartan vs Lisinopril</b>			
Mazayev et al. (vs lisinopril , 1998 n=75/15 follow-up: 4 wk	Valsartan, 40 mg, 80mg, 160mg twice daily versus lisinopril 10mg once daily	patients with chronic heart failure	Parallel groups NA Russia

## References

NCT00090259 ,  
 HEAAL, 2009:  
 VALIDD, 2007:  
 ARCH-J, 2003:  
 CHARM-Alternative, 2003:  
 Mitrovic et al., 2003:  
 SPICE, 2000:  
 STRETCH, 1999:  
 Losartan Phase III U.S., 1995:  
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 Mazayev et al. (vs placebo), 1998:  
 ELITE, 1997:  
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 RESOLVD (candesartan alone), 1999:  
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 losartan phase II US, 1996:  
 Dickstein et al., 1995:

Lang et al., 1997:  
 REPLACE, 2001:  
 HEAVEN, 2002:  
 Mazayev et al. (vs lisinopril, 1998:

## 2 ARBs added to ACEI

Trial	Treatments	Patients	Trials design and methods
<b>candesartan+ACE inhibitor vs ACE inhibitor only</b>			
<b>RESOLVD association , 1999</b> n=332/109 follow-up: 43 wk	Candesartan, 4 mg, 8mg daily, plus enalapril, 10 mg twice daily versus 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 multicenter
<b>CHARM-Added , 2003</b> n=1276/1272 follow-up: Median, 41 mo	Candesartantarget dose 32 mg once daily versus Placebo	patients with New York Heart Association functional class IIIIV CHF and left-ventricular ejection fraction40% or lower, and who were being treated with ACE inhibitors.	Parallel groups double blind 26 countries
<b>eprosartan+ACE inhibitor vs ACE inhibitor only</b>			
<b>ADEPT , 2001</b> n=18/18 follow-up: 8 wk	Eprosartan, 400 to 800 mg twice daily versus Placebo	patients with stable New York Heart Association class II-IV CHF receiving ACE inhibitor therapy	Parallel groups double blind
<b>irbesartan+ACE inhibitor vs ACE inhibitor only</b>			
<b>Tonkon et al. , 2000</b> n=57/52 follow-up: 12 wk	Irbesartan, 150 mg daily (plus ACE inhibitor) versus Placebo (plus ACE inhibitor)	patients with heart failure (New York Heart Association functional class II and III) and left ventricular ejection fraction (LVEF) <or = 40% received stable doses of ACE inhibitors and diuretics	Parallel groups double blind
<b>losartan+ACE inhibitor vs ACE inhibitor only</b>			
<b>Hamroff et al. , 1999</b> n=16/17 follow-up: 6 mo	Losartan, 50 mg daily (plus ACE inhibitor) versus Placebo (plus ACE inhibitor)	patients with severe congestive heart failure (NYHA III-IV) despite treatment with maximally recommended or tolerated doses of ACE inhibitors	Parallel groups double blind
<b>valsartan+ACE inhibitor vs ACE inhibitor only</b>			
<b>V-HeFT , 1999</b> n=55/28 follow-up: 4 wk	Valsartan 80 mg and 160mg twice daily (plus ACE inhibitor) versus Placebo (plus usual ACE inhibitor)	Patients with stable symptomatic congestive heart failure (CHF) receiving long-term ACE inhibitor therapy (NYHA functional class II,III, or IV) and PCWP >or=to 15 mm Hg	Parallel groups Double blind US
<b>Val-HeFT , 2001</b> n=2511/2499 follow-up: 23 mo	Valsartan, 160 mg twice daily (plus ACE inhibitor) versus Placebo (plus ACE inhibitor)	patients with heart failure of New York Heart Association (NYHA) class II, III, or IV	Parallel groups Double blind 16 countries

## References

**RESOLVD association, 1999:**

**CHARM-Added, 2003:**

**ADEPT, 2001:**

**Tonkon et al., 2000:**

**Hamroff et al., 1999:**

**V-HeFT, 1999:**

**Val-HeFT, 2001:**

## 3 About TrialResults-center.org

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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.

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