

# Clinical trials of valsartan

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

## 1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
<b>Valsartan+ACE inhibitor vs ACE inhibitor only</b>			
<b>VALIANT (valsartan+capropril) , 2003</b> n=4885/4909 follow-up: Median, 24.7 mo	Valsartan, 40 mg twice daily, plus captopril, 25 mg three times daily versus Captopril, 25 mg 3 times daily	patients within 10 days of a MI complicated by HF	Parallel groups Double blind 24
<b>Valsartan vs Captopril</b>			
<b>VALIANT (valsartan alone) , 2003</b> n=4909/4909 follow-up: Median, 24.7 mo	Valsartan, 160 mg twice daily versus Captopril, 50 mg 3 times daily	patients within 10 days of a MI complicated by HF	Parallel groups Double blind 24

More details and results :

- angiotensin-receptor blockers for acute myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q253>

## References

### **VALIANT (valsartan+capropril), 2003:**

Pfeffer MA, McMurray JJ, Velazquez EJ, Rouleau JL, Kober L, Maggioni AP, Solomon SD, Swedberg K, Van de Werf F, White H, Leimberger JD, Henis M, Edwards S, Zelenkofske S, Sellers MA, Califf RM Valsartan, captopril, or both in myocardial infarction complicated by heart failure, left ventricular dysfunction, or both. N Engl J Med 2003 Nov 13;349:1893-906 [[14610160](#)]

### **VALIANT (valsartan alone), 2003:**

Pfeffer MA, McMurray JJ, Velazquez EJ, Rouleau JL, Kober L, Maggioni AP, Solomon SD, Swedberg K, Van de Werf F, White H, Leimberger JD, Henis M, Edwards S, Zelenkofske S, Sellers MA, Califf RM Valsartan, captopril, or both in myocardial infarction complicated by heart failure, left ventricular dysfunction, or both. N Engl J Med 2003 Nov 13;349:1893-906 [[14610160](#)]

## 2 hypertension

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>valsartan vs amlodipine</b>			
<b>VALUE , 2004</b> [NCT00129233] n=7649/7596 follow-up: 4.2 y (mean)	valsartan based regimen versus amlodipine based regimen	patients, aged 50 years or older with treated or untreated hypertension and high risk of cardiac events	Parallel groups Double blind 31 countries
<b>NAGOYA HEART , 2011</b> <i>unpublished</i> [NCT00129233] n=575/575 follow-up: 3.2 y median	blood-pressure-lowering therapy based on valsartan; blood-pressure goal of <130/80 mm Hg versus blood-pressure-lowering therapy based on amlodipine; blood-pressure goal of <130/80 mm Hg	patients with hypertension with type 2 diabetes or impaired glucose tolerance	Parallel groups open Japan
<b>Valsartan vs Captopril</b>			
<b>VALIANT/Val , 2003</b> n=4909/4909 follow-up: 2.1 y	Valsartan versus Captopril	patients with myocardial infarction complicated by left ventricular systolic dysfunction, heart failure, or both	Parallel groups double-blind
<b>Valsartan + captopril vs Captopril</b>			
<b>VALIANT/Val+Cap , 2003</b> n=4885/4909 follow-up: 2.1 y	Valsartan + captopril versus Captopril	patients with myocardial infarction complicated by left ventricular systolic dysfunction, heart failure, or both	Parallel groups double-blind

More details and results :

- anti hypertensive agents for hypertension in diabetic patients at <http://www.trialresultscenter.org/go-Q10>
- anti hypertensive agents for hypertension in all type of patient at <http://www.trialresultscenter.org/go-Q13>
- 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 with additional risk factor at <http://www.trialresultscenter.org/go-Q686>

## References

### VALUE, 2004:

Julius S, Kjeldsen SE, Weber M, Brunner HR, Ekman S, Hansson L, Hua T, Laragh J, McInnes GT, Mitchell L, Plat F, Schork A, Smith B, Zanchetti A Outcomes in hypertensive patients at high cardiovascular risk treated with regimens based on valsartan or amlodipine: the VALUE randomised trial. *Lancet* 2004 Jun 19;363:2022-31 [15207952]

### NAGOYA HEART, 2011:

unpublished

Matsushita K, Muramatsu T, Kondo T, Maeda K, Shintani S, Murohara T Rationale and design of the NAGOYA HEART Study: comparison between valsartan and amlodipine regarding morbidity and mortality in patients with hypertension and glucose intolerance. J Cardiol 2010;56:111-7 [20409690] 10.1016/j.jjcc.2010.03.004  
**VALIANT/Val, 2003:**

Pfeffer MA, McMurray JJ, Velazquez EJ, Rouleau JL, Kber L, Maggioni AP, Solomon SD, Swedberg K, Van de Werf F, White H, Leimberger JD, Henis M, Edwards S, Zelenkofske S, Sellers MA, Califf RM Valsartan, captopril, or both in myocardial infarction complicated by heart failure, left ventricular dysfunction, or both. N Engl J Med 2003;349:1893-906 [14610160]

McMurray J, Solomon S, Pieper K, Reed S, Rouleau J, Velazquez E, White H, Howlett J, Swedberg K, Maggioni A, Kber L, Van de Werf F, Califf R, Pfeffer M The effect of valsartan, captopril, or both on atherosclerotic events after acute myocardial infarction: an analysis of the Valsartan in Acute Myocardial Infarction Trial (VALIANT). J Am Coll Cardiol 2006;47:726-33 [16487836]

**VALIANT/Val+Cap, 2003:**

Pfeffer MA, McMurray JJ, Velazquez EJ, Rouleau JL, Kber L, Maggioni AP, Solomon SD, Swedberg K, Van de Werf F, White H, Leimberger JD, Henis M, Edwards S, Zelenkofske S, Sellers MA, Califf RM Valsartan, captopril, or both in myocardial infarction complicated by heart failure, left ventricular dysfunction, or both. N Engl J Med 2003;349:1893-906 [14610160]

McMurray J, Solomon S, Pieper K, Reed S, Rouleau J, Velazquez E, White H, Howlett J, Swedberg K, Maggioni A, Kber L, Van de Werf F, Califf R, Pfeffer M The effect of valsartan, captopril, or both on atherosclerotic events after acute myocardial infarction: an analysis of the Valsartan in Acute Myocardial Infarction Trial (VALIANT). J Am Coll Cardiol 2006;47:726-33 [16487836]

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### 3 heart failure

Trial	Treatments	Patients	Trials design and methods
<b>sacubitril/valsartan vs enalapril</b>			
<b>PARADIGM-HF , 2014</b> [NCT01035255] n=NA follow-up:	-	-	
<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>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>valsartan+ACE inhibitor vs ACE inhibitor only</b>			

continued...

Trial	Treatments	Patients	Trials design and methods
V-HeFT , 1999 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 $\geq$ 15 mm Hg	Parallel groups Double blind US
Val-HeFT , 2001 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
<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

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 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>
- combined inhibition of ACE and neprilysin for heart failure in all type of patients at <http://www.trialresultscenter.org/go-Q637>

## References

### PARADIGM-HF, 2014:

McMurray JJ, Packer M, Desai AS, Gong J, Lefkowitz MP, Rizkala AR, Rouleau JL, Shi VC, Solomon SD, Swedberg K, Zile MR Angiotensin-Neprilysin Inhibition versus Enalapril in Heart Failure. N Engl J Med 2014 Aug 30; [25176015] [10.1056/NEJMoa1409077](https://doi.org/10.1056/NEJMoa1409077)

#### VALIDD, 2007:

American College of Cardiology Annual Scientific Session, New Orleans, LA, March 2007. [0]

Solomon SD, Janardhanan R, Verma A, Bourgoun M, Daley WL, Purkayastha D, Lacourcire Y, Hippler SE, Fields H, Naqvi TZ, Mulvagh SL, Arnold JM, Thomas JD, Zile MR, Aurigemma GP Effect of angiotensin receptor blockade and antihypertensive drugs on diastolic function in patients with hypertension and diastolic dysfunction: a randomised trial. Lancet 2007 Jun 23;369:2079-87 [17586303]

#### Mazayev et al. (vs placebo), 1998:

Mazayev VP, Fomina IG, Kazakov EN, Sulimov VA, Zvereva TV, Lyusov VA, Orlov VA, Olbinskaya LI, Bolshakova TD, Sullivan J, Spormann DO Valsartan in heart failure patients previously untreated with an ACE inhibitor. Int J Cardiol 1998 Aug;65:239-46 [9740480]

#### V-HeFT, 1999:

Baruch L, Anand I, Cohen IS, Ziesche S, Judd D, Cohn JN Augmented short- and long-term hemodynamic and hormonal effects of an angiotensin receptor blocker added to angiotensin converting enzyme inhibitor therapy in patients with heart failure. Vasodilator Heart Failure Trial (V-HeFT) Study Group. Circulation 1999 May 25;99:2658-64 [10338459]

#### Val-HeFT, 2001:

Cohn JN, Tognoni G A randomized trial of the angiotensin-receptor blocker valsartan in chronic heart failure. N Engl J Med 2001 Dec 6;345:1667-75 [11759645]

#### HEAVEN, 2002:

Willenheimer R, Helmers C, Pantev E, Rydberg E, Lofdahl P, Gordon A Safety and efficacy of valsartan versus enalapril in heart failure patients. Int J Cardiol 2002 Oct;85:261-70 [12208593]

#### Mazayev et al. (vs lisinopril, 1998:

Mazayev VP, Fomina IG, Kazakov EN, Sulimov VA, Zvereva TV, Lyusov VA, Orlov VA, Olbinskaya LI, Bolshakova TD, Sullivan J, Spormann DO Valsartan in heart failure patients previously untreated with an ACE inhibitor. Int J Cardiol 1998 Aug;65:239-46 [9740480]

## 4 miscellaneous

Trial	Treatments	Patients	Trials design and methods
<b>valsartan vs amlodipine</b>			
VALUE, 2004 [NCT00129233] n=7649/7596 follow-up: 4.2 y (mean)	valsartan based regimen versus amlodipine based regimen	patients, aged 50 years or older with treated or untreated hypertension and high risk of cardiac events	Parallel groups Double blind 31 countries

More details and results :

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

## References

#### VALUE, 2004:

Julius S, Kjeldsen SE, Weber M, Brunner HR, Ekman S, Hansson L, Hua T, Laragh J, McInnes GT, Mitchell L, Plat F, Schork A, Smith B, Zanchetti A Outcomes in hypertensive patients at high cardiovascular risk treated with regimens based on valsartan or amlodipine: the VALUE randomised trial. Lancet 2004 Jun 19;363:2022-31 [15207952]

## 5 atrial fibrillation

Trial	Treatments	Patients	Trials design and methods
<b>valsartan vs placebo</b>			
Val-HeFT (AF ancillary study) , 2003 n=2506/2494 follow-up: 1.92 y	valsartan versus placebo	Heart failure	
GISSI-AF (Disertori) , 2009  [NCT00376272] n=722/720 follow-up: 1 year	valsartan versus placebo	patients in sinus rhythm but with either two or more documented episodes of atrial fibrillation in the previous 6 months or successful cardioversion for atrial fibrillation in the previous 2 weeks and with underlying cardiovascular disease, diabetes, or left atrial enlargement	Parallel groups double blind

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>

## References

### Val-HeFT (AF ancillary study), 2003:

Maggioni ALR, Carson PE, et al Valsartan reduces the incidence of atrial fibrillation in the patients with heart failure in the Val-HeFT Trial Circulation 2003;108:507

### GISSI-AF (Disertori), 2009:

Disertori M, Latini R, Barlera S, Franzosi MG, Staszewsky L, Maggioni AP, Lucci D, Di Pasquale G, Tognoni G Valsartan for prevention of recurrent atrial fibrillation. N Engl J Med 2009 Apr 16;360:1606-17 [19369667]

## 6 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
<b>valsartan vs placebo</b>			
NAVIGATOR valsartan , 2010 [NCT00097786] n=4631/4675 follow-up: 5 years	valsartan up to 160 mg daily versus placebo	subjects with impaired glucose tolerance and either CV disease or CV risk factors	Factorial plan double-blind 40 countries
<b>valsartan vs amlodipine</b>			
NAGOYA HEART , 2011 <i>unpublished</i> [NCT00129233] n=575/575 follow-up: 3.2 y median	blood-pressure-lowering therapy based on valsartan; blood-pressure goal of <130/80 mm Hg versus blood-pressure-lowering therapy based on amlodipine; blood-pressure goal of <130/80 mm Hg	patients with hypertension with type 2 diabetes or impaired glucose tolerance	Parallel groups open Japan

More details and results :

- anti hypertensive agents for diabetes type 2 in patients with hypertension at <http://www.trialresultscenter.org/go-Q83>
- prevention for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q341>
- anti hypertensive agents for diabetes type 2 in patients with or without hypertension at <http://www.trialresultscenter.org/go-Q414>
- prevention for diabetes type 2 in people with impaired glucose tolerance at <http://www.trialresultscenter.org/go-Q416>
- angiotensin-receptor blockers for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q427>
- angiotensin renin system blockade for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q438>

## References

### NAVIGATOR valsartan, 2010:

Effect of Valsartan on the Incidence of Diabetes and Cardiovascular Events. N Engl J Med 2010 Mar 16; [20228403] 10.1056/NEJMoa1001121

Krum H, McMurray JJ, Horton E, Gerlock T, Holzhauer B, Zuurman L, Haffner SM, Bethel MA, Holman RR, Califf RM Baseline characteristics of the Nateglinide and Valsartan Impaired Glucose Tolerance Outcomes Research (NAVIGATOR) trial population: comparison with other diabetes prevention trials. Cardiovasc Ther 2010;28:124-32 [20184589] 10.1111/j.1755-5922.2010.00146.x

### NAGOYA HEART, 2011:

unpublished

Matsushita K, Muramatsu T, Kondo T, Maeda K, Shintani S, Murohara T Rationale and design of the NAGOYA HEART Study: comparison between valsartan and amlodipine regarding morbidity and mortality in patients with hypertension and glucose intolerance. J Cardiol 2010;56:111-7 [20409690] 10.1016/j.jjcc.2010.03.004

## 7 patients at high risk for cardiovascular events

Trial	Treatments	Patients	Trials design and methods
<b>valsartan vs amlodipine</b>			
VALUE , 2004 [NCT00129233] n=7649/7596 follow-up: 4.2 y (mean)	valsartan based regimen versus amlodipine based regimen	patients, aged 50 years or older with treated or untreated hypertension and high risk of cardiac events	Parallel groups Double blind 31 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

### VALUE, 2004:

∞ Julius S, Kjeldsen SE, Weber M, Brunner HR, Ekman S, Hansson L, Hua T, Laragh J, McInnes GT, Mitchell L, Plat F, Schork A, Smith B, Zanchetti A Outcomes in hypertensive patients at high cardiovascular risk treated with regimens based on valsartan or amlodipine: the VALUE randomised trial. Lancet 2004 Jun 19;363:2022-31 [15207952]

## 8 impaired fasting glucose

Trial	Treatments	Patients	Trials design and methods
<b>valsartan vs placebo</b>			
NAVIGATOR valsartan , 2010 [NCT00097786] n=4631/4675 follow-up: 5 years	valsartan up to 160 mg daily versus placebo	subjects with impaired glucose tolerance and either CV disease or CV risk factors	Factorial plan double-blind 40 countries

More details and results :

- prevention for impaired fasting glucose in all type of patients at <http://www.trialresultscenter.org/go-Q342>

## References

### **NAVIGATOR valsartan, 2010:**

Effect of Valsartan on the Incidence of Diabetes and Cardiovascular Events. N Engl J Med 2010 Mar 16;: [20228403] [10.1056/NEJMoa1001121](#)

Krum H, McMurray JJ, Horton E, Gerlock T, Holzhauer B, Zuurman L, Haffner SM, Bethel MA, Holman RR, Califf RM Baseline characteristics of the Nateglinide and Valsartan Impaired Glucose Tolerance Outcomes Research (NAVIGATOR) trial population: comparison with other diabetes prevention trials. Cardiovasc Ther 2010;28:124-32 [20184589] [10.1111/j.1755-5922.2010.00146.x](#)

Entry terms: captopril, SQ-14534, SQ 14534, SQ14534, SQ-14225, SQ 14225, SQ14225, Capoten, Lopirin, , valsartan, Diovan, Tareg, KalpressMiten, Provas, Vals, walsartan, CGP 48933, Nisis, Aventis brand of valsartan,