

Clinical trials of irbesartan

TrialResults-center www.trialresultscenter.org

1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
irbesartan vs control			
GLOBAL ongoing [NCT00125645] n=NA follow-up: 3 months	irbesartan versus usual care	patients with acute myocardial infarction, a wall motion score >1.3 (EF>0.40) and signs of diastolic dysfunction	Parallel groups open

More details and results :

- angiotensin-Converting Enzyme Inhibitors for acute myocardial infarction in systematic early treatment (with or without sign of HF) at <http://www.trialresultscenter.org/go-Q145>
- angiotensin-Converting Enzyme Inhibitors for acute myocardial infarction in patients with or without HF at <http://www.trialresultscenter.org/go-Q146>

References

GLOBAL, :

ongoing trial NCT00125645

2 hypertension

Trial	Treatments	Patients	Trials design and methods
irbesartan vs placebo			
IDNT (irbesartan vs pbo) , 2001 n=579/569 follow-up: 2.6 y	Irbesartan 300mg/d (target 135/85) versus placebo	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double-blind worldwide

continued...

Trial	Treatments	Patients	Trials design and methods
IRMA 2 , 2001 n=404/207 follow-up: 2 years	irbesartan 150 mg daily or 300 mg daily versus placebo	hypertensive patients with type 2 diabetes and microalbuminuria	Parallel groups double-blind multinational
IDNT (irbesartan vs pbo) , 2001 n=579/569 follow-up: 2.6 years	Irbesartan 300 mg daily versus placebo	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double blind Worldwide
IPDM (150mg) , 2001 n=195/201 follow-up: 2 years	irbesartan 150 mg daily versus placebo	hypertensive patients with type 2 diabetes and microalbuminuria	Parallel groups double-blind Worldwide
irbesartan vs amlodipine			
IDNT (irbesartan vs amlodipine) , 2001 n=579/567 follow-up: 26y	Irbesartan 300mg/d (with a target of 135/85) versus amlodipine 10mg/d (with a target of 135/85)	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double-blind worldwide
IDNT (irbesartan vs amlodipine) , 2001 n=579/567 follow-up: 2.6 years	Irbesartan 300 mg daily versus amlodipine 10 mg daily	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double blind Worldwide

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>
- anti hypertensive agents for hypertension in nephropathy at <http://www.trialresultscenter.org/go-Q19>
- angiotensin-receptor blockers for hypertension in all diseases requiring ACEi (HF, CHD, HT,...) at <http://www.trialresultscenter.org/go-Q125>

References

IDNT (irbesartan vs pbo), 2001:

Lewis EJ, Hunsicker LG, Clarke WR, Berl T, Pohl MA, Lewis JB, Ritz E, Atkins RC, Rohde R, Raz I Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. N Engl J Med 2001;345:851-60 [11565517]

Lewis EJ, Hunsicker LG, Clarke WR, Berl T, Pohl MA, Lewis JB, Ritz E, Atkins RC, Rohde R, Raz I Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. N Engl J Med 2001;345:851-60 [11565517]

IRMA 2, 2001:

Parving HH, Lehnert H, Brchner-Mortensen J, Gomis R, Andersen S, Arner P The effect of irbesartan on the development of diabetic nephropathy in patients with type 2 diabetes. N Engl J Med 2001;345:870-8 [11565519] 10.1056/NEJMoa011489

IDNT (irbesartan vs placebo), 2001:

Lewis EJ, Hunsicker LG, Clarke WR, Berl T, Pohl MA, Lewis JB, Ritz E, Atkins RC, Rohde R, Raz I Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. N Engl J Med 2001;345:851-60 [11565517]

IPDM (150mg), 2001:

Parving HH, Lehnert H, Brchner-Mortensen J, Gomis R, Andersen S, Arner P The effect of irbesartan on the development of diabetic nephropathy in patients with type 2 diabetes. N Engl J Med 2001;345:870-8 [11565519]

IDNT (irbesartan vs amlodipine), 2001:

Lewis EJ, Hunsicker LG, Clarke WR, Berl T, Pohl MA, Lewis JB, Ritz E, Atkins RC, Rohde R, Raz I Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. N Engl J Med 2001;345:851-60 [11565517]

IDNT (irbesartan vs amlodipine), 2001:

Lewis EJ, Hunsicker LG, Clarke WR, Berl T, Pohl MA, Lewis JB, Ritz E, Atkins RC, Rohde R, Raz I Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. N Engl J Med 2001;345:851-60 [11565517]

3 heart failure

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Trial	Treatments	Patients	Trials design and methods
irbesartan+ACE inhibitor vs ACE inhibitor only			
Tonkon et al., 2000 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

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 already receiving ACE inhibitor at <http://www.trialresultscenter.org/go-Q68>

References

Tonkon et al., 2000:

Tonkon M, Awan N, Niazi I, Hanley P, Baruch L, Wolf RA, Block AJ A study of the efficacy and safety of irbesartan in combination with conventional therapy, including ACE inhibitors, in heart failure. Irbesartan Heart Failure Group. Int J Clin Pract 2000 Jan-Feb;54:11-4, 16-8 [10750252]

4 miscellaneous

Trial	Treatments	Patients	Trials design and methods
irbesartan vs placebo			
IDNT (irbesartan vs placebo), 2001 n=579/569 follow-up: 2.6 y	Irbesartan 300mg/d (target 135/85) versus placebo	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double-blind worldwide
IRMA 2 , 2001 n=404/207 follow-up: 2 years	irbesartan 150 mg daily or 300 mg daily versus placebo	hypertensive patients with type 2 diabetes and microalbuminuria	Parallel groups double-blind multinational
irbesartan vs amlodipine			
IDNT (irbesartan vs amlodipine) , 2001 n=579/567 follow-up: 26y	Irbesartan 300mg/d (with a target of 135/85) versus amlodipine 10mg/d (with a target of 135/85)	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double-blind worldwide



More details and results :

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

References

IDNT (irbesartan vs placebo), 2001:

Lewis EJ, Hunsicker LG, Clarke WR, Berl T, Pohl MA, Lewis JB, Ritz E, Atkins RC, Rohde R, Raz I Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. N Engl J Med 2001;345:851-60 [11565517]

Lewis EJ, Hunsicker LG, Clarke WR, Berl T, Pohl MA, Lewis JB, Ritz E, Atkins RC, Rohde R, Raz I Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. N Engl J Med 2001;345:851-60 [11565517]

IRMA 2 , 2001:

Parving HH, Lehnert H, Brchner-Mortensen J, Gomis R, Andersen S, Arner P The effect of irbesartan on the development of diabetic nephropathy in patients with type 2 diabetes. N Engl J Med 2001;345:870-8 [11565519] 10.1056/NEJMoa011489

IDNT (irbesartan vs amlodipine), 2001:

Lewis EJ, Hunsicker LG, Clarke WR, Berl T, Pohl MA, Lewis JB, Ritz E, Atkins RC, Rohde R, Raz I Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. N Engl J Med 2001;345:851-60 [11565517]

5 atrial fibrillation

Trial	Treatments	Patients	Trials design and methods
irbesartan vs control			
Madrid , 2002 n=79/75 follow-up: 254 d (range 60-710)	irbesartan versus control	atrial fibrillation	Parallel groups open
irbesartan vs placebo			
ACTIVE I , 2009 [NCT00249795] n=4518/4498 follow-up: 4.1 years	irbesartan 300mg once daily versus placebo	patients with atrial fibrillation and with a systolic blood pressure of at least 110 mmHg associated with at least one major risk of vascular events	Factorial plan double blind

More details and results :

- prevention for atrial fibrillation in patient with history of atrial fibrillation at <http://www.trialresultscenter.org/go-Q328>

References

Madrid, 2002:

Madrid AH, Bueno MG, Rebollo JM, Marn I, Pea G, Bernal E, Rodriguez A, Cano L, Cano JM, Cabeza P, Moro C Use of irbesartan to maintain sinus rhythm in patients with long-lasting persistent atrial fibrillation: a prospective and randomized study. Circulation 2002;106:331-6 [12119249]

ACTIVE I, 2009:

Yusuf S, Healey JS, Pogue J, Chrolavicius S, Flather M, Hart RG, Hohnloser SH, Joyner CD, Pfeffer MA, Connolly SJ Irbesartan in patients with atrial fibrillation. N Engl J Med 2011;364:928-38 [21388310] 10.1056/NEJMoa1008816

Yusuf S, Healey JS, Pogue J, Chrolavicius S, Flather M, Hart RG, Hohnloser SH, Joyner CD, Pfeffer MA, Connolly SJ Irbesartan in patients with atrial fibrillation. N Engl J Med 2011 Mar 10;364:928-38 [21388310]

6 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
irbesartan vs placebo			
IDNT (irbesartan vs pbo) , 2001 n=579/569 follow-up: 2.6 years	Irbesartan 300 mg daily versus placebo	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double blind Worldwide

continued...

Trial	Treatments	Patients	Trials design and methods
IPDM (150mg) , 2001 n=195/201 follow-up: 2 years	irbesartan 150 mg daily versus placebo	hypertensive patients with type 2 diabetes and microalbuminuria	Parallel groups double-blind Worldwide
irbesartan vs amlodipine			
IDNT (irbesartan vs amlodipine) , 2001 n=579/567 follow-up: 2.6 years	Irbesartan 300 mg daily versus amlodipine 10 mg daily	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double blind Worldwide

More details and results :

- anti hypertensive agents for diabetes type 2 in patients with hypertension at <http://www.trialresultscenter.org/go-Q83>
- anti hypertensive agents for diabetes type 2 in patients with or without hypertension at <http://www.trialresultscenter.org/go-Q414>
- 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>

6

References

IDNT (irbesartan vs placebo), 2001:

Lewis EJ, Hunsicker LG, Clarke WR, Berl T, Pohl MA, Lewis JB, Ritz E, Atkins RC, Rohde R, Raz I Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. N Engl J Med 2001;345:851-60 [11565517]

IPDM (150mg), 2001:

Parving HH, Lehnert H, Brchner-Mortensen J, Gomis R, Andersen S, Arner P The effect of irbesartan on the development of diabetic nephropathy in patients with type 2 diabetes. N Engl J Med 2001;345:870-8 [11565519]

IDNT (irbesartan vs amlodipine), 2001:

Lewis EJ, Hunsicker LG, Clarke WR, Berl T, Pohl MA, Lewis JB, Ritz E, Atkins RC, Rohde R, Raz I Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. N Engl J Med 2001;345:851-60 [11565517]

7 diabetic kidney disease

Trial	Treatments	Patients	Trials design and methods
irbesartan vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
IDNT (irbesartan vs placebo) , 2001 n=579/569 follow-up: 2.6 years	Irbesartan 300 mg daily versus placebo	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double blind Worldwide
IPDM (150mg) , 2001 n=195/201 follow-up: 2 years	irbesartan 150 mg daily versus placebo	hypertensive patients with type 2 diabetes and microalbuminuria	Parallel groups double-blind Worldwide
irbesartan vs amlodipine			
IDNT (irbesartan vs amlodipine) , 2001 n=579/567 follow-up: 2.6 years	Irbesartan 300 mg daily versus amlodipine 10 mg daily	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double blind Worldwide

More details and results :

- All mechanism for diabetic kidney disease in all type of patients at <http://www.trialresultscenter.org/go-Q667>

References

IDNT (irbesartan vs placebo), 2001:

Lewis EJ, Hunsicker LG, Clarke WR, Berl T, Pohl MA, Lewis JB, Ritz E, Atkins RC, Rohde R, Raz I Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. N Engl J Med 2001;345:851-60 [11565517]

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IDNT (irbesartan vs amlodipine), 2001:

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Entry terms: Aprovel, Avapro, Karvea