

# Clinical trials of All mechanism for diabetic kidney disease in all type of patients

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## 1 ACE inhibitor

Trial	Treatments	Patients	Trials design and methods
<b>ACEI ARB vs ARB alone</b>			
<b>VA NEPHRON-D</b> <i>ongoing</i> [NCT00555217] n=NA follow-up:	Combination of ARB and ACEI versus Monotherapy ARB (	-	

## References

VA NEPHRON-D, 0:

## 2 angiotensin receptor blocker

Trial	Treatments	Patients	Trials design and methods
<b>irbesartan vs placebo</b>			
<b>IDNT (irbesartan vs pbo)</b> , <b>2001</b> 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
<b>IPDM (150mg)</b> , <b>2001</b> 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
<b>losartan vs placebo</b>			
<b>RENAAL</b> , <b>2001</b> n=751/762 follow-up: 3.4 y	losartan 50 to 100 mg once daily versus placebo	patients with type 2 diabetes and nephropathy	Parallel groups double-blind America, Europe, Asia
<b>olmesartan vs placebo</b>			
<b>ORIENT</b> [NCT00141453] n=282/284 follow-up:	olmesartan versus placebo	patients with diabetic Nephropathy and overt proteinuria secondary to type 2 diabetes mellitus	Parallel groups double-blind Japan, Hong Kong
<b>irbesartan vs amlodipine</b>			

continued...

Trial	Treatments	Patients	Trials design and methods
<b>IDNT (irbesartan vs amlodipine), 2001</b> 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
<b>telmisartan vs enalapril</b>			
<b>DETAIL, 2004</b> n=120/130 follow-up: 5 year	telmisartan 80 mg daily versus enalapril 20 mg daily	subjects with type 2 diabetes and early nephropathy	Parallel groups double-blind
<b>temisartan vs enalapril</b>			
<b>DETAIL, 2004</b> n=120/130 follow-up: 5 years	telmisartan 80 mg daily versus enalapril 20 mg daily	subjects with type 2 diabetes and early nephropathy	Parallel groups double-blind northern Europe

## 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](#)]

### **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](#)]

### **RENAAL, 2001:**

Brenner BM, Cooper ME, de Zeeuw D, Keane WF, Mitch WE, Parving HH, Remuzzi G, Snapinn SM, Zhang Z, Shahinfar S Effects of losartan on renal and cardiovascular outcomes in patients with type 2 diabetes and nephropathy. N Engl J Med 2001;345:861-9 [[11565518](#)]

### **ORIENT, :**

### **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](#)]

### **DETAIL, 2004:**

Barnett AH, Bain SC, Bouter P, Karlberg B, Madsbad S, Jervell J, Mustonen J Angiotensin-receptor blockade versus converting-enzyme inhibition in type 2 diabetes and nephropathy. N Engl J Med 2004;351:1952-61 [[15516696](#)] [10.1056/NEJMoa042274](#)

### **DETAIL, 2004:**

Barnett AH, Bain SC, Bouter P, Karlberg B, Madsbad S, Jervell J, Mustonen J Angiotensin-receptor blockade versus converting-enzyme inhibition in type 2 diabetes and nephropathy. N Engl J Med 2004;351:1952-61 [[15516696](#)] [10.1056/NEJMoa042274](#)

## 3 angiotensin-converting enzyme inhibitors

Trial	Treatments	Patients	Trials design and methods
<b>fosinopril vs control</b>			

continued...

Trial	Treatments	Patients	Trials design and methods
<b>Fogari , 2002</b> n=104/103 follow-up: NA	amlodipine plus fosinopril (5/10 to 15/30 mg/day versus amlodipine (5 to 15 mg/day)	hypertensive patients with type 2 diabetes and microalbuminuria	Parallel groups NA
<b>ramipril vs placebo</b>			
<b>DIABHYCAR , 2004</b> n=2443/2469 follow-up: median 4 years	ramipril 1.25 mg/day versus placebo	patients with type 2 diabetes who have microalbuminuria or proteinuria	Parallel groups double-blind Europe, North Africa

## References

### Fogari, 2002:

Fogari R, Preti P, Zoppi A, Rinaldi A, Corradi L, Pasotti C, Poletti L, Marasi G, Derosa G, Mugellini A, Voglini C, Lazzari P Effects of amlodipine fosinopril combination on microalbuminuria in hypertensive type 2 diabetic patients. *Am J Hypertens* 2002;15:1042-9 [[12460699](#)]

### DIABHYCAR, 2004:

Marre M, Lievre M, Chatellier G, Mann JF, Passa P, Mnard J Effects of low dose ramipril on cardiovascular and renal outcomes in patients with type 2 diabetes and raised excretion of urinary albumin: randomised, double blind, placebo controlled trial (the DIABHYCAR study). *BMJ* 2004;328:495 [[14960504](#)] [10.1136/bmj.37970.629537.0D](#)

## 4 calcium-channel blockers

Trial	Treatments	Patients	Trials design and methods
<b>amlodipine vs placebo</b>			
<b>IDNT (amlodipine vs PBO) , 2001</b> n=567/569 follow-up: 2.6 years	Amlodipine 10 mg daily versus placebo	hypertensive patients with nephropathy due to type 2 diabetes	Parallel groups double-blind Worldwide

## References

### IDNT (amlodipine 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](#)]

Hunsicker LG, Atkins RC, Lewis JB, Braden G, de Zeeuw DJ, DeFerra G, Drury P, Locatelli F, Wiegmann TB, Lewis EJ Impact of irbesartan, blood pressure control, and proteinuria on renal outcomes in the Irbesartan Diabetic Nephropathy Trial. *Kidney Int Suppl* 2004;:S99-101 [[15485429](#)] [10.1111/j.1523-1755.2004.09223.x](#)

POHL, MA, CORDONNIER, DJ, SPITALOWITZ, S, et al, FOR THE COLLABORATIVE STUDY GROUP Impact of angiotensin receptor blockade with irbesartan on renal function at different systolic blood pressure (SBP) levels in type 2 diabetic nephropathy. *J Am Soc Nephrol* 2002 13: 650A,

Pohl MA, Blumenthal S, Cordonnier DJ, De Alvaro F, Deferrari G, Eisner G, Esmatjes E, Gilbert RE, Hunsicker LG, de Faria JB, Mangili R, Moore J Jr, Reisin E, Ritz E, Scherthaner G, Spitalowitz S, Tindall H, Rodby RA, Lewis EJ Independent and additive impact of blood pressure control and angiotensin II receptor blockade on renal outcomes in the irbesartan diabetic nephropathy trial: clinical implications and limitations. *J Am Soc Nephrol* 2005;16:3027-37 [[16120823](#)] [10.1681/ASN.2004110919](#)

## 5 endothelin receptor antagonist (ERA)

Trial	Treatments	Patients	Trials design and methods
<b>atrasentan vs placebo</b>			
SONAR <i>ongoing</i> [NCT01858532] n=4148 follow-up:	Atrasentan Oral daily low dose for 48 months. versus Placebo	subjects with type 2 diabetes and nephropathy who are treated with the maximum tolerated labeled daily dose of a Renin Angiotensin System inhibitor	

### References

SONAR, 0:

## 6 non steroidal MRA

Trial	Treatments	Patients	Trials design and methods
<b>finerenone vs placebo</b>			
FIDELIO-DKD <i>ongoing</i> [NCT02540993] n=NA follow-up:	-	-	
FIGARO-DKD <i>ongoing</i> [NCT02545049] n=NA follow-up:	-	-	double-blind

### References

FIDELIO-DKD, 0:

FIGARO-DKD, 0:

## 7 SGLT-2 inhibitor

Trial	Treatments	Patients	Trials design and methods
<b>canagliflozin vs placebo</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>CREDESCENCE</b> <i>ongoing</i> [NCT02065791] n=4200 follow-up: 66 months	Canagliflozin 100 mg over-encapsulated tablet orally once daily versus placebo	with type 2 diabetes mellitus, Stage 2 or 3 chronic kidney disease and macroalbuminuria, who are receiving standard of care including a maximum tolerated labeled daily dose of an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker	Parallel groups double-blind

## References

CREDESCENCE, 0:

## 8 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

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.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

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