

# Clinical trials of intensive therapy for diabetes type 2 in all type of patients

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## 1 a

Trial	Treatments	Patients	Trials design and methods
<b>vs</b>			
Study 3002 n=NA follow-up:	-	-	
Study 3006 n=NA follow-up:	-	-	
Study 3102 n=NA follow-up:	-	-	
Study 4001 n=NA follow-up:	-	-	
Study 4002 n=NA follow-up:	-	-	
Study 4012 n=NA follow-up:	-	-	
Study 4013 n=NA follow-up:	-	-	
<b>insulin detemir vs glargine</b>			
Fadini , 2011 n=NA	-	-	
<b>insulin lispro protamine suspension plus lispro vs glargine plus lispro</b>			
Koivisto , 2011 n=NA	-	-	
<b>insulin glargine plus insulin glulisine vs premixed insulin analogues</b>			
Levin , 2011 n=NA	-	-	

## References

Study 3002, 0:

Study 3006, 0:

Study 3102, 0:

**Study 4001, 0:**

**Study 4002, 0:**

**Study 4012, 0:**

**Study 4013, 0:**

**Fadini, 2011:**

Fadini GP, de Kreutzenberg SV, Mariano V, Boscaro E, Bertolini F, Mancuso P, Quarna J, Marescotti M, Agostini C, Tiengo A, Avogaro A, Optimized glycaemic control achieved with add-on basal insulin therapy improves indexes of endothelial damage and regeneration in type 2 diabetic patients with macroangiopathy: a randomized crossover trial comparing detemir versus glargine. *Diabetes Obes Metab* 2011;13:718-25. [21410861] [10.1111/j.1463-1326.2011.01396.x](https://doi.org/10.1111/j.1463-1326.2011.01396.x)

**Koivisto, 2011:**

Koivisto V, Cleall S, Pontiroli AE, Giugliano D, Comparison of insulin lispro protamine suspension versus insulin glargine once daily in basal-bolus therapies with insulin lispro in type 2 diabetes patients: a prospective randomized open-label trial. *Diabetes Obes Metab* 2011;13:1149-57. [21819517] [10.1111/j.1463-1326.2011.01484.x](https://doi.org/10.1111/j.1463-1326.2011.01484.x)

**Levin, 2011:**

Levin PA, Zhang Q, Mersey JH, Lee FY, Bromberger LA, Bhushan M, Bhushan R, Glycemic control with insulin glargine plus insulin glulisine versus premixed insulin analogues in real-world practices: a cost-effectiveness study with a randomized pragmatic trial design. *Clin Ther* 2011;33:841-50. [21719107] [10.1016/j.clinthera.2011.05.091](https://doi.org/10.1016/j.clinthera.2011.05.091)

## 2 induced HbA1c reduction

Trial	Treatments	Patients	Trials design and methods
<b>glitazone vs conventional treatment</b>			
<b>PROactive , 2005</b> [NCT00174993] n=2605/2633 follow-up: 34.5 months	pioglitazone titrated 15-45 mg daily versus standard treatment	patients with type 2 diabetes who had evidence of macrovascular disease	Parallel groups double blind 19 countries
<b>intensive glycemic control vs conventional treatment</b>			
<b>ACCORD , 2008</b> [NCT00000620] n=5128/5123 follow-up: 3.5y (5y)	very intensive glycemic control through currently available means (targeting a glycosylated hemoglobin <6% ) during a mean of 3.7 years versus standard glycemic control (targeting a glycosylated hemoglobin 7.0-7.9% )	patients with type 2 diabetes mellitus at high risk of death and stroke (pre-existing heart disease or two or more additional risk factors for heart disease)	Factorial plan open USA, Canada
<b>ADDITION , 2010</b> [NCT00237549] n=1678/1379 follow-up: 5 year	intensive multifactorial treatment versus routine care	patients with newly diagnosed type 2 diabetes	Parallel groups open Denmark, United Kingdom, the Netherlands
<b>ADVANCE , 2008</b> [NCT00145925] n=5571/5569 follow-up: median 5 y	intensive glucose-lowering treatments HbA1C <=6.5% using gliclazide(modified release) plus other drugs versus standard glucose-lowering treatments (targetglycated hemoglobin levels defined on the basisof local guidelines)	patients with type 2 diabetes	Parallel groups open 20 countries

continued...

Trial	Treatments	Patients	Trials design and methods
Kumamoto (primary prev) , 1995 n=28/27 follow-up: 8.0y	intensive glycemic control with multiple insulin injection treatment versus conventional insulin injection treatment (1-2 daily injections)	patients with non-insulin-dependent diabetes mellitus and with no retinopathy and urinary albumin excretions <30 mg/24 h	Parallel groups open Japan
Kumamoto (secondary prev) , 1995 n=27/28 follow-up: 8.0y	multiple insulin injection treatment versus conventional insulin injection treatment (1-2 daily injections)	patients with non-insulin-dependent diabetes mellitus and simple retinopathy	Parallel groups open Japan
Steno 2 , 2003 n=80/80 follow-up: 7.8 y	targeted, intensified, multifactorial intervention versus conventional treatment on modifiable risk factors for cardiovascular disease	patients with type 2 diabetes and microalbuminuria	Parallel groups open Denmark
UKPDS 33 , 1998 n=2729/1138 follow-up: 10.3 y	intensive policy with a sulphonylurea (chlorpropamide, glibenclamide, or glipizide) or with insulin; fasting plasma glucose <6.0 mmol/L versus conventional policy with diet	newly diagnosed patients with type 2 diabetes who after 3 months diet treatment had a mean of two fasting plasma glucose concentrations of 61150 mmol/L	Parallel groups open UK
VA CSDM , 1997 n=75/78 follow-up: 2.3y	intensive glycemic control (stepped plan from 1 evening injection of insulin, alone or with glipizide, to multiple daily injections, target to attain near-normal glycemia levels) versus standard treatment (1 insulin injection every morning)	non-insulin-dependent diabetes mellitus patients	Parallel groups open USA
VADT , 2008 [NCT00032487] n=892/899 follow-up: 5.6y	intensive glucose control versus standard glucose control	military veterans who had a suboptimal response to therapy for type 2 diabetes	Parallel groups open US

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### 3 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.

TrialResults-center is non-profit and self-funded.