

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

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## 1 a

Trial	Treatments	Patients	Trials design and methods
<b>lispro twice daily + NPH insulin vs regular insulin + NPH insulin</b>			
Vignati n=NA follow-up:	twice-daily insulin lispro in combination with NPH human insulin versus regular human insulin in combination with NPH human insulin	-	

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### Vignati, 0:

Vignati L, Anderson JH, Iversen PW, Efficacy of insulin lispro in combination with NPH human insulin twice per day in patients with insulin-dependent or non-insulin-dependent diabetes mellitus. Multicenter Insulin Lispro Study Group. Clin Ther ;19:1408-21. [[9444449](#)]

## 2 AAA

Trial	Treatments	Patients	Trials design and methods
<b>lispro mixture vs glargine once daily</b>			
Chan META-ANALYSIS , 2009 n=NA follow-up:	insulin lispro mixtures, given twice or thrice daily versus insulin glargine, given once daily	patients with type 2 diabetes treated with metformin	

## References

### Chan META-ANALYSIS, 2009:

Chan JY, Leyk M, Frier BM, Tan MH, Relationship between HbA1c and hypoglycaemia in patients with type 2 diabetes treated with different insulin regimens in combination with metformin. Diabetes Metab Res Rev 2009;25:224-31. [[19156705](#)] [10.1002/dmrr.929](#)

## 3 basal + bolus

Trial	Treatments	Patients	Trials design and methods
<b>insulin glulisine + glargine vs glargine once daily</b>			
Owens , 2011 n=49/57 follow-up: 3 months	basal+bolus (single dose of insulin glulisine immediately prior to the main meal) versus basal insulin (glargin)	patients withT2DM using any basal insulin and HbA1c >7.0% after 3-month of insulin glargine titrated to optimize fasting bloodglucose control	Parallel groups open-label US, UK, Russia
<b>lispro + NPH vs NPH twice daily</b>			
Ceriello , 2007 n=NA follow-up: 12 weeks	premeal insulin lispro+bedtime neutral protamine Hagedorn (NPH) versus twice-daily NPH	patients with type 2 diabetes treated by a 2-month lead-in with twice-daily NPH treatment	Cross over open-label

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### Owens, 2011:

Owens DR, Luzio SD, Sert-Langeron C, Riddle MC Effects of initiation and titration of a single pre-prandial dose of insulin glulisine while continuing titrated insulin glargine in type 2 diabetes: a 6-month 'proof-of-concept' study. Diabetes Obes Metab 2011;13:1020-7 [[21679291](#)] [10.1111/j.1463-1326.2011.01459.x](#)

### Ceriello, 2007:

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## 4 basal insulin

Trial	Treatments	Patients	Trials design and methods
<b>glargine vs</b>			
Eliashewitz n=231/250 follow-up: 24 weeks	-	-	
Fonseca n=52/48 follow-up: 28 weeks	-	-	
Massi n=293/285 follow-up: 52 weeks	-	-	
Pan n=220/223 follow-up: 24 weeks	-	-	
Philis-Tsimikas n=334/164 follow-up: 20 weeks	-	-	
Rosenstock n=259/259 follow-up: 28 weeks	-	-	

continued...

Trial	Treatments	Patients	Trials design and methods
Wang n=16/8 follow-up: 12 weeks	-	-	
Yki-Yarvinen n=214/208 follow-up: 52 weeks	-	-	
Yki-Yarvinen n=61/49 follow-up: 36 weeks	-	-	
Yokoyama n=31/31 follow-up: 26 weeks	-	-	
<b>morning insulin glargine vs bedtime insulin glargine</b>			
Fritche n=463/232 follow-up: 24 weeks	morning insulin glargine versus bedtime insulin glargine	patients with type 2 diabetes previously treated with oral antidiabetic agents	open
<b>glargine vs NPH</b>			
Riddle POC 4002 Glargine , 2003 n=NA follow-up:	bedtime glargine versus NPH once daily	overweight men and women with inadequate glycemic control (HbA(1c) >7.5% ) on one or two oral agents	Parallel groups open-label
HOE 901/3002 , 2000 n=NA follow-up:	bedtime insulin glargine versus bedtime NPH insulin	insulin-naive type 2 diabetic patients with poor glycemic control on oral antidiabetic agents	
<b>glargine vs NPH + SU</b>			
Riddle n=367/389 follow-up: 24 weeks	bedtime glargine versus NPH	overweight men and women with inadequate glycemic control (HbA(1c) >7.5% ) on one or two oral agents	open
<b>insulin detemir vs NPH insulin</b>			
Hermansen n=236/237 follow-up: 26 weeks	insulin detemir twice-daily versus NPH insulin	insulin-naive people with type 2 diabetes	
<b>detemir vs NPH insulin (add on aspart)</b>			
65279;Haak n=341/164 follow-up: 65279;26 weeks	insulin detemir either once or twice daily according to their pretrial insulin treatment versus NPH insulin	patients with type 2 diabetes	open

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**Philis-Tsimikas , :**

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## 5 insulin therapy

Trial	Treatments	Patients	Trials design and methods
<b>insulin vs control</b>			
<b>UGDP</b> n=414/205 follow-up:	-	-	
<b>UKPDS 33</b> n=911/896 follow-up:	-	-	

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### UGDP, :

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### UKPDS 33, :

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## 6 lixisenatide

Trial	Treatments	Patients	Trials design and methods
<b>lixisenatide vs glargine once daily</b>			
<b>GETGOAL-L</b> <i>unpublished</i> [NCT00715624] n=328/167 follow-up: 24 weeks	AVE0010 (10,15 and 20 g) in association with basal insulin, with or without metformin versus placebo on top basal insulin	Type 2 diabetes mellitus insufficiently controlled with basal insulin with or without metformin	Parallel groups double-blind USA

## References

### GETGOAL-L, 0:

## 7 once daily premixed insulin analogue

Trial	Treatments	Patients	Trials design and methods
<b>BIAsp 70/30 twice daily vs glargine once daily</b>			
<b>Kalra , 2010</b> n=76/79 follow-up: 26 weeks	BIAsp 30 once-daily biphasic insulin aspart 70/30 (NovoMix 30 FlexPen) versus insulin glargine once daily	Asian subjects with type 2 diabetes inadequately controlled with oral anti-diabetic drugs	Parallel groups open-label Asia
<b>INITIATE (Raskin) , 2005</b> n=117/116 follow-up: 28 weeks	BIAsp 70/30, prebreakfast and presupper versus once-daily insulin glargine	insulin-naive patients with HbA(1c) values $\geq 8.0\%$ on $>1,000$ mg/day metformin alone or in combination with other OADs	Parallel groups open-label
<b>Strojek , 2009</b> n=239/241 follow-up: 26 weeks	biphasic insulin aspart 30 (BIAsp 30) once daily versus insulin glargine once daily	patients with type 2 diabetes inadequately controlled with oral drugs	Parallel groups open-label

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Moses AC, Raskin P, Khutoryansky N Does serum 1,5-anhydroglucitol establish a relationship between improvements in HbA1c and postprandial glucose excursions? Supportive evidence utilizing the differential effects between biphasic insulin aspart 30 and insulin glargine. *Diabet Med* 2008 Feb;25:200-5 [[18290862](#)] [10.1111/j.1464-5491.2008.02384.x](#)

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## 8 thrice daily premixed insulin analogue

Trial	Treatments	Patients	Trials design and methods
<b>premix lispro 50/50 thrice time vs glargine once daily</b>			
<b>Robbins , 2007</b> [NCT00191464] n=158/159 follow-up: 24 weeks	lispro mix 50/50 (50% insulin lispro protamine suspension [ILPS] and 50% lispro) T1D for 24 weeks versus insulin glargine QD at bedtime	patients with type 2 diabetes mellitus and an HbA(1c) level of 6.5% to 11.0% , who were receiving metformin and/or a sulfonylurea with a stable dose of 0 to 2 daily insulin injections	Parallel groups open-label Australia, Greece, India, The Netherlands, Poland, Puerto Rico, and the United States

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Trial	Treatments	Patients	Trials design and methods
<b>Kazda , 2006</b> n=54/53 follow-up: 24 week	3x daily lispro mid mixture (MidMix; 50% lispro, 50% protaminated lispro), versus 1x daily insulin glargine	patients with type 2 diabetes starting insulin treatment	Parallel groups open-label Germany
<b>premix lispro thrice daily vs glargine once daily</b>			
<b>Jacober , 2006</b> n=60/60 follow-up: 4 months	intensive insulin lispro mixture therapy for 4 months versus once-daily insulin glargine	insulin-naive patients with type 2 diabetes receiving oral antidiabetes agents	Cross over

## References

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## 9 twice-daily premixed insulin analogue

Trial	Treatments	Patients	Trials design and methods
<b>BIAsp 70/30 twice daily vs detemir once daily</b>			
<b>4T (Holman) , 2007</b> [ISRCTN51125379] n=235/234 follow-up: 1 year	biphasic insulin aspart (NovoMix 30) twice daily versus basal insulin detemir once daily (twice if required)	patients with a suboptimal glycated hemoglobin level (7.0 to 10.0% ) who were receiving maximally tolerated doses of metformin and sulfonylurea	Parallel groups
<b>BIAsp 70/30 twice daily vs glargine once daily</b>			
<b>Kalra , 2010</b> n=76/79 follow-up: 26 weeks	BIAsp 30 once-daily biphasic insulin aspart 70/30 (NovoMix 30 FlexPen) versus insulin glargine once daily	Asian subjects with type 2 diabetes inadequately controlled with oral anti-diabetic drugs	Parallel groups open-label Asia

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>INITIATE (Raskin) , 2005</b> n=117/116 follow-up: 28 weeks	BIAsp 70/30, prebreakfast and presupper versus once-daily insulin glargine	insulin-naive patients with HbA(1c) values >/=8.0% on >1,000 mg/day metformin alone or in combination with other OADs	Parallel groups open-label
<b>Strojek , 2009</b> n=239/241 follow-up: 26 weeks	biphasic insulin aspart 30 (BIAsp 30) once daily versus insulin glargine once daily	patients with type 2 diabetes inadequately controlled with oral drugs	Parallel groups open-label
<b>premix lispro 75/25 twice daily vs glargine once daily</b>			
<b>DURABLE (Buse) DOUBLONS , 2011</b> n=NA follow-up:	lispro mix 75/25 twice daily versus once-daily insulin glargine	type 2 diabetes patients	
<b>DURABLE (Buse) , 2009</b> [NCT00279201] n=1045/1046 follow-up: 24 weeks	twice-daily lispro mix 75/25 versus daily glargine	patients with type 2 diabetes mellitus failing to achieve control with starter insulin treatment and continuing oral antihyperglycemic drugs	Parallel groups
<b>Malone , 2004</b> n=105/105 follow-up: 16 week	mixture of 75% insulin lispro protamine suspension and 25% insulin lispro (Mix 75/25) BID versus insulin glargine QD	patients with type 2 diabetes beginning insulin therapy	Cross over open-label USA
<b>Malone , 2005</b> n=97/97 follow-up: 32 weeks	insulin lispro mixture (25% insulin lispro and 75% NPL) twice daily versus once-daily insulin glargine	patients with Type 2 diabetes inadequately controlled with intermediate insulin, or insulin plus oral agent(s) combination therapy	Cross over
<b>BIAsp 70/30 twice daily vs NPH twice daily</b>			
<b>Christiansen , 2003</b> n=NA follow-up: 18 weeks	Twice daily biphasic insulin aspart (BIAsp30) versus NPH insulin twice daily	patients with type 2 diabetes not optimally controlled by oral hypoglycaemic agents, NPH insulin or a combination of both	Parallel groups double-blind
<b>premix aspart70/30 twice daily vs once daily insulin glargine</b>			
<b>INITIATE (Raskin) DOUBLON , 2008</b> n=NA follow-up:	biphasic insulin aspart 70/30 (BIAsp 70/30, prebreakfast and presupper) versus once-daily insulin glargine	insulin-naive patients with HbA1c values 8.0% on 1,000 mg/day metformin alone or in combination with other OADs	Parallel groups

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## 10 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.