

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 |
|--|---|----------|---------------------------|
| lispro twice daily + NPH insulin vs regular insulin + NPH insulin | | | |
| 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 | - | |

References

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 |
|--|---|---|---------------------------|
| lispro mixture vs glargine once daily | | | |
| 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](https://doi.org/10.1002/dmrr.929)

3 basal + bolus

| Trial | Treatments | Patients | Trials design and methods |
|--|--|---|---|
| insulin glulisine + glargine vs glargine once daily | | | |
| 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 |
| lispro + NPH vs NPH twice daily | | | |
| 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 |

References

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:

Ceriello A, Del Prato S, Bue-Valleskey J, Beattie S, Gates J, de la Pea A, Malone J, Premeal insulin lispro plus bedtime NPH or twice-daily NPH in patients with type 2 diabetes: acute postprandial and chronic effects on glycemic control and cardiovascular risk factors. J Diabetes Complications ;21:20-7. [[17189870](#)] [10.1016/j.jdiacomp.2005.11.005](#)

2

4 basal insulin

| Trial | Treatments | Patients | Trials design and methods |
|---|------------|----------|---------------------------|
| glargine vs | | | |
| 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 | - | - | |
| morning insulin glargine vs bedtime insulin glargine | | | |
| 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 |
| glargine vs NPH | | | |
| 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 | |
| glargine vs NPH + SU | | | |
| 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 |
| insulin detemir vs NPH insulin | | | |
| Hermansen n=236/237 follow-up: 26 weeks | insulin detemir twice-daily versus NPH insulin | insulin-naive people with type 2 diabetes | |
| detemir vs NPH insulin (add on aspart) | | | |
| 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 |

References

Eliaeschewitz , :

Eliaeschewitz FG, Calvo C, Valbuena H, Ruiz M, Aschner P, Villena J, Ramirez LA, Jimenez J Therapy in type 2 diabetes: insulin glargine vs. NPH insulin both in combination with glimepiride. Arch Med Res 2006;37:495-501 [16715577]

Fonseca , :

Fonseca V, Bell DS, Berger S, Thomson S, Mecca TE A comparison of bedtime insulin glargine with bedtime neutral protamine hagedorn insulin in patients with type 2 diabetes: subgroup analysis of patients taking once-daily insulin in a multicenter, randomized, parallel group study. *Am J Med Sci* 2004;328:274-80 [[15545844](#)]

Massi , :

Massi Benedetti M, Humburg E, Dressler A, Ziemer M A one-year, randomised, multicentre trial comparing insulin glargine with NPH insulin in combination with oral agents in patients with type 2 diabetes. *Horm Metab Res* 2003;35:189-96 [[12734781](#)] [10.1055/s-2003-39080](#)

Pan , :

Pan CY, Sinnassamy P, Chung KD, Kim KW Insulin glargine versus NPH insulin therapy in Asian Type 2 diabetes patients. *Diabetes Res Clin Pract* 2007;76:111-8 [[17011662](#)] [10.1016/j.diabres.2006.08.012](#)

Philis-Tsimikas , :

Philis-Tsimikas A, Charpentier G, Clauson P, Ravn GM, Roberts VL, Thorsteinsson B Comparison of once-daily insulin detemir with NPH insulin added to a regimen of oral antidiabetic drugs in poorly controlled type 2 diabetes. *Clin Ther* 2006;28:1569-81 [[17157113](#)] [10.1016/j.clinthera.2006.10.020](#)

Rosenstock , :

Rosenstock J, Davies M, Home PD, Larsen J, Koenen C, Scherthaner G A randomised, 52-week, treat-to-target trial comparing insulin detemir with insulin glargine when administered as add-on to glucose-lowering drugs in insulin-naive people with type 2 diabetes. *Diabetologia* 2008;51:408-16 [[18204830](#)] [10.1007/s00125-007-0911-x](#)

Wang , :

Wang XL, Lu JM, Pan CY, Mu YM, Dou JT, Ba JM, Wang X Evaluation of the superiority of insulin glargine as basal insulin replacement by continuous glucose monitoring system. *Diabetes Res Clin Pract* 2007;76:30-6 [[16979255](#)] [10.1016/j.diabres.2006.08.005](#)

Yki-Yarvinen , :

Yki-Jrvinen H, Juurinen L, Alvarsson M, Bystedt T, Caldwell I, Davies M, Lahdenper S, Nijpels G, Vhtalo M Initiate Insulin by Aggressive Titration and Education (INITIATE): a randomized study to compare initiation of insulin combination therapy in type 2 diabetic patients individually and in groups. *Diabetes Care* 2007;30:1364-9 [[17384341](#)] [10.2337/dc06-1357](#)

Yki-Yarvinen , :

Yki-Jrvinen H, Dressler A, Ziemer M Less nocturnal hypoglycemia and better post-dinner glucose control with bedtime insulin glargine compared with bedtime NPH insulin during insulin combination therapy in type 2 diabetes. *HOE 901/3002 Study Group. Diabetes Care* 2000;23:1130-6 [[10937510](#)]

Yokoyama , :

Yokoyama H, Tada J, Kamikawa F, Kanno S, Yokota Y, Kuramitsu M Efficacy of conversion from bedtime NPH insulin to morning insulin glargine in type 2 diabetic patients on basal-prandial insulin therapy. *Diabetes Res Clin Pract* 2006;73:35-40 [[16513202](#)] [10.1016/j.diabres.2005.12.009](#)

Fritsche , :

Fritsche A, Schweitzer MA, Hring HU Glimepiride combined with morning insulin glargine, bedtime neutral protamine hagedorn insulin, or bedtime insulin glargine in patients with type 2 diabetes. A randomized, controlled trial. *Ann Intern Med* 2003;138:952-9 [[12809451](#)]

Riddle POC 4002 Glargine, 2003:

Riddle MC, Rosenstock J, Gerich J The treat-to-target trial: randomized addition of glargine or human NPH insulin to oral therapy of type 2 diabetic patients. *Diabetes Care* 2003;26:3080-6 [[14578243](#)]

HOE 901/3002, 2000:

Yki-Jrvinen H, Dressler A, Ziemer M Less nocturnal hypoglycemia and better post-dinner glucose control with bedtime insulin glargine compared with bedtime NPH insulin during insulin combination therapy in type 2 diabetes. *HOE 901/3002 Study Group. Diabetes Care* 2000;23:1130-6 [[10937510](#)]

Riddle , :

Riddle MC, Rosenstock J, Gerich J The treat-to-target trial: randomized addition of glargine or human NPH insulin to oral therapy of type 2 diabetic patients. *Diabetes Care* 2003;26:3080-6 [[14578243](#)]

Hermansen , :

Hermansen K, Davies M, Derezhinski T, Martinez Ravn G, Clauson P, Home P A 26-week, randomized, parallel, treat-to-target trial comparing insulin detemir with NPH insulin as add-on therapy to oral glucose-lowering drugs in insulin-naive people with type 2 diabetes. *Diabetes Care* 2006;29:1269-74 [[16732007](#)] [10.2337/dc05-1365](#)

65279;Haak , :

Haak T, Tiengo A, Draeger E, Suntum M, Waldhul W Lower within-subject variability of fasting blood glucose and reduced weight gain with insulin detemir compared to NPH insulin in patients with type 2 diabetes. *Diabetes Obes Metab* 2005;7:56-64 [[15642076](#)] [10.1111/j.1463-1326.2004.00373.x](#)

5 insulin therapy

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

References

UGDP, :

Effects of hypoglycemic agents on vascular complications in patients with adult-onset diabetes. VIII. Evaluation of insulin therapy: final report. *Diabetes* 1982 Nov;31 Suppl 5:1-81 [[6757026](#)]

UKPDS 33, :

Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group. *Lancet* 1998 Sep 12;352:837-53 [[9742976](#)]

6 lixisenatide

| Trial | Treatments | Patients | Trials design and methods |
|--|---|---|--|
| lixisenatide vs glargine once daily | | | |
| GETGOAL-L <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 |
|---|---|--|---------------------------------------|
| BIAsp 70/30 twice daily vs glargine once daily | | | |
| Kalra , 2010 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 |
| INITIATE (Raskin) , 2005 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 |
| Strojek , 2009 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 |

References

Kalra, 2010:

Kalra S, Plata-Que T, Kumar D, Mumtaz M, Sndergaard F, Kozlovski P, Bebakar WM, Initiation with once-daily BIAsp 30 results in superior outcome compared to insulin glargine in Asians with type 2 diabetes inadequately controlled by oral anti-diabetic drugs. *Diabetes Res Clin Pract* 2010;88:282-8. [[20363044](#)] [10.1016/j.diabres.2010.03.004](#)

INITIATE (Raskin), 2005:

Brod M, Cobden D, Lammert M, Bushnell D, Raskin P, Examining correlates of treatment satisfaction for injectable insulin in type 2 diabetes: lessons learned from a clinical trial comparing biphasic and basal analogues. *Health Qual Life Outcomes* 2007;5:8. [[17286868](#)] [10.1186/1477-7525-5-8](#)

Raskin P, Allen E, Hollander P, Lewin A, Gabbay RA, Hu P, Bode B, Garber A, , Initiating insulin therapy in type 2 Diabetes: a comparison of biphasic and basal insulin analogs. *Diabetes Care* 2005;28:260-5. [[15677776](#)]

Goodall G, Jendle JH, Valentine WJ, Munro V, Brandt AB, Ray JA, Roze S, Foos V, Palmer AJ Biphasic insulin aspart 70/30 vs. insulin glargine in insulin nave type 2 diabetes patients: modelling the long-term health economic implications in a Swedish setting. *Int J Clin Pract* 2008;62:869-76 [[18479280](#)] [10.1111/j.1742-1241.2008.01766.x](#)

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](#)

Strojek, 2009:

Strojek K, Bebakar WM, Khutsoane DT, Pesic M, Smahelov A, Thomsen HF, Kalra S, Once-daily initiation with biphasic insulin aspart 30 versus insulin glargine in patients with type 2 diabetes inadequately controlled with oral drugs: an open-label, multinational RCT. *Curr Med Res Opin* 2009;25:2887-94. [[19821654](#)] [10.1185/03007990903354674](#)

8 thrice daily premixed insulin analogue

| Trial | Treatments | Patients | Trials design and methods |
|--|---|---|--|
| premix lispro 50/50 thrice time vs glargine once daily | | | |
| Robbins , 2007 [NCT00191464] n=158/159 follow-up: 24 weeks | lispro mix 50/50 (50% insulin lispro protamine suspension [ILPS] and 50% lispro) TID 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 |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|--|---|--|--|
| Kazda , 2006 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 |
| premix lispro thrice daily vs glargine once daily | | | |
| Jacober , 2006 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

Robbins, 2007:

Robbins DC, Beisswenger PJ, Ceriello A, Goldberg RB, Moses RG, Pagkalos EM, Milicevic Z, Jones CA, Sarwat S, Tan MH Mealttime 50/50 basal + prandial insulin analogue mixture with a basal insulin analogue, both plus metformin, in the achievement of target HbA1c and pre- and postprandial blood glucose levels in patients with type 2 diabetes: a multinational, 24-week, randomized, open-label, parallel-group comparison. Clin Ther 2007;29:2349-64 [18158076] [10.1016/j.clinthera.2007.11.016](https://doi.org/10.1016/j.clinthera.2007.11.016)

Robbins DC, Beisswenger PJ, Ceriello A, et al. Thrice-daily lispro mid mixture plus metformin improved glycemic control better than glargine plus metformin in patients with type 2 diabetes. Diabetes. 2006;55(Suppl 1):554-P. A132. Abstract

Kazda, 2006:

Kazda C, Hlstrunk H, Helsberg K, Langer F, Forst T, Hanefeld M, Prandial insulin substitution with insulin lispro or insulin lispro mid mixture vs. basal therapy with insulin glargine: a randomized controlled trial in patients with type 2 diabetes beginning insulin therapy. J Diabetes Complications ;20:145-52. [16632233] [10.1016/j.jdiacomp.2005.09.004](https://doi.org/10.1016/j.jdiacomp.2005.09.004)

Jacober, 2006:

Jacober SJ, Scism-Bacon JL, Zagar AJ A comparison of intensive mixture therapy with basal insulin therapy in insulin-naive patients with type 2 diabetes receiving oral antidiabetes agents. Diabetes Obes Metab 2006;8:448-55 [16776752] [10.1111/j.1463-1326.2006.00605.x](https://doi.org/10.1111/j.1463-1326.2006.00605.x)

9 twice-daily premixed insulin analogue

| Trial | Treatments | Patients | Trials design and methods |
|---|--|---|---------------------------------------|
| BIAsp 70/30 twice daily vs detemir once daily | | | |
| 4T (Holman) , 2007 [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 |
| BIAsp 70/30 twice daily vs glargine once daily | | | |
| Kalra , 2010 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...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|----------------------------------|
| INITIATE (Raskin) , 2005 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 |
| Strojek , 2009 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 |
| premix lispro 75/25 twice daily vs glargine once daily | | | |
| DURABLE (Buse) DOUBLONS , 2011 n=NA follow-up: | lispro mix 75/25 twice daily versus once-daily insulin glargine | type 2 diabetes patients | |
| DURABLE (Buse) , 2009 [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 |
| Malone , 2004 n=105/105 follow-up: 16 week | mixture of 75% insulin lispro protamine suspensionand 25% insulin lispro (Mix 75/25) BID versus insulin glargine QD | patients with type 2 diabetes beginning insulin therapy | Cross over open-label USA |
| Malone , 2005 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 |
| BIAsp 70/30 twice daily vs NPH twice daily | | | |
| Christiansen , 2003 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 |
| premix aspart70/30 twice daily vs once daily insulin glargine | | | |
| INITIATE (Raskin) DOUBLON , 2008 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 |

8

References

4T (Holman), 2007:

Holman RR, Thorne KI, Farmer AJ, Davies MJ, Keenan JF, Paul S, Levy JC, , Addition of biphasic, prandial, or basal insulin to oral therapy in type 2 diabetes. N Engl J Med 2007;357:1716-30. [[17890232](#)] [10.1056/NEJMoa075392](#)

Kalra, 2010:

Kalra S, Plata-Que T, Kumar D, Mumtaz M, Sndergaard F, Kozlovski P, Bebakar WM, Initiation with once-daily BIAsp 30 results in superior outcome compared to insulin glargine in Asians with type 2 diabetes inadequately controlled by oral anti-diabetic drugs. Diabetes Res Clin Pract 2010;88:282-8. [[20363044](#)] [10.1016/j.diabres.2010.03.004](#)

INITIATE (Raskin), 2005:

Brod M, Cobden D, Lammert M, Bushnell D, Raskin P, Examining correlates of treatment satisfaction for injectable insulin in type 2 diabetes: lessons learned from a clinical trial

comparing biphasic and basal analogues. *Health Qual Life Outcomes* 2007;5:8. [17286868] [10.1186/1477-7525-5-8](#)

Raskin P, Allen E, Hollander P, Lewin A, Gabbay RA, Hu P, Bode B, Garber A, , Initiating insulin therapy in type 2 Diabetes: a comparison of biphasic and basal insulin analogs. *Diabetes Care* 2005;28:260-5. [15677776]

Goodall G, Jendle JH, Valentine WJ, Munro V, Brandt AB, Ray JA, Roze S, Foos V, Palmer AJ Biphasic insulin aspart 70/30 vs. insulin glargine in insulin nave type 2 diabetes patients: modelling the long-term health economic implications in a Swedish setting. *Int J Clin Pract* 2008;62:869-76 [18479280] [10.1111/j.1742-1241.2008.01766.x](#)

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](#)

Strojek, 2009:

Strojek K, Bebakar WM, Khutsoane DT, Pesic M, Smahelov A, Thomsen HF, Kalra S, Once-daily initiation with biphasic insulin aspart 30 versus insulin glargine in patients with type 2 diabetes inadequately controlled with oral drugs: an open-label, multinational RCT. *Curr Med Res Opin* 2009;25:2887-94. [19821654] [10.1185/03007990903354674](#)

DURABLE (Buse) DOUBLONS, 2011:

DURABLE (Buse), 2009:

Buse JB, Wolffenbittel BH, Herman WH, Hippler S, Martin SA, Jiang HH, Shenouda SK, Fahrback JL, The DURAbility of Basal versus Lispro mix 75/25 insulin Efficacy (DURABLE) trial: comparing the durability of lispro mix 75/25 and glargine. *Diabetes Care* 2011;34:249-55. [21270182] [10.2337/dc10-1701](#)

Miser WF, Arakaki R, Jiang H, Scism-Bacon J, Anderson PW, Fahrback JL, Randomized, open-label, parallel-group evaluations of basal-bolus therapy versus insulin lispro premixed therapy in patients with type 2 diabetes mellitus failing to achieve control with starter insulin treatment and continuing oral antihyperglycemic drugs: a noninferiority intensification substudy of the DURABLE trial. *Clin Ther* 2010;32:896-908. [20685497] [10.1016/j.clinthera.2010.05.001](#)

Wolffenbittel BH, Klaff LJ, Bhushan R, Fahrback JL, Jiang H, Martin S, Initiating insulin therapy in elderly patients with Type 2 diabetes: efficacy and safety of lispro mix 25 vs. basal insulin combined with oral glucose-lowering agents. *Diabet Med* 2009;26:1147-55. [19929994] [10.1111/j.1464-5491.2009.02824.x](#)

Buse JB, Wolffenbittel BH, Herman WH, Shemonsky NK, Jiang HH, Fahrback JL, Scism-Bacon JL, Martin SA, DURAbility of basal versus lispro mix 75/25 insulin efficacy (DURABLE) trial 24-week results: safety and efficacy of insulin lispro mix 75/25 versus insulin glargine added to oral antihyperglycemic drugs in patients with type 2 diabetes. *Diabetes Care* 2009;32:1007-13. [19336625] [10.2337/dc08-2117](#)

Buse JB, Wolffenbittel BH, Herman WH, Shemonsky NK, Jiang HH, Fahrback JL, Scism-Bacon JL, Martin SA, DURAbility of basal versus lispro mix 75/25 insulin efficacy (DURABLE) trial 24-week results: safety and efficacy of insulin lispro mix 75/25 versus insulin glargine added to oral antihyperglycemic drugs in patients with type 2 diabetes. *Diabetes Care* 2009;32:1007-13. [19336625] [10.2337/dc08-2117](#)

Fahrback J, Jacober S, Jiang H, Martin S The DURABLE trial study design: comparing the safety, efficacy, and durability of insulin glargine to insulin lispro mix 75/25 added to oral antihyperglycemic agents in patients with type 2 diabetes. *J Diabetes Sci Technol* 2008 Sep;2:831-8 [19885269]

Malone, 2004:

Malone JK, Kerr LF, Campaigne BN, Sachson RA, Holcombe JH, , Combined therapy with insulin lispro Mix 75/25 plus metformin or insulin glargine plus metformin: a 16-week, randomized, open-label, crossover study in patients with type 2 diabetes beginning insulin therapy. *Clin Ther* 2004;26:2034-44. [15823767] [10.1016/j.clinthera.2004.12.015](#)

Malone, 2005:

Malone JK, Bai S, Campaigne BN, Reviriego J, Augendre-Ferrante B, Twice-daily pre-mixed insulin rather than basal insulin therapy alone results in better overall glycaemic control in patients with Type 2 diabetes. *Diabet Med* 2005;22:374-81. [15787659] [10.1111/j.1464-5491.2005.01511.x](#)

Christiansen, 2003:

Christiansen JS, Vaz JA, Metelko Z, Bogoev M, Dedov I, Twice daily biphasic insulin aspart improves postprandial glycaemic control more effectively than twice daily NPH insulin, with low risk of hypoglycaemia, in patients with type 2 diabetes. *Diabetes Obes Metab* 2003;5:446-54. [14617231]

INITIATE (Raskin) DOUBLON, 2008:

Goodall G, Jendle JH, Valentine WJ, Munro V, Brandt AB, Ray JA, Roze S, Foos V, Palmer AJ, Biphasic insulin aspart 70/30 vs. insulin glargine in insulin nave type 2 diabetes patients: modelling the long-term health economic implications in a Swedish setting. *Int J Clin Pract* 2008;62:869-76. [18479280] [10.1111/j.1742-1241.2008.01766.x](#)

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;25:200-5. [18290862] [10.1111/j.1464-5491.2008.02384.x](#)

Ray JA, Valentine WJ, Roze S, Nicklasson L, Cobden D, Raskin P, Garber A, Palmer AJ, Insulin therapy in type 2 diabetes patients failing oral agents: cost-effectiveness of biphasic insulin aspart 70/30 vs. insulin glargine in the US. *Diabetes Obes Metab* 2007;9:103-13. [17199725] [10.1111/j.1463-1326.2006.00581.x](https://doi.org/10.1111/j.1463-1326.2006.00581.x)

Raskin P, Allen E, Hollander P, Lewin A, Gabbay RA, Hu P, Bode B, Garber A Initiating insulin therapy in type 2 Diabetes: a comparison of biphasic and basal insulin analogs. *Diabetes Care* 2005 Feb;28:260-5 [15677776]

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.