

Clinical trials of empagliflozin

TrialResults-center www.trialresultscenter.org

1 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
empagliflozin vs			
Kadowaki , 2013 n=NA follow-up:	-	Japanese patients with type 2 diabetes	
Kadowaki , 2014 n=NA	-	-	
empagliflozin vs Glimepiride + MET			
Ridderstrale , 2014 [NCT01167881] n=NA follow-up: 104 w	BI 10773 dose plus metformin versus Glimepiride 1-4 mg plus metformin	-	USA
empagliflozin vs linagliptin (add-on MET)			
DeFronzo , 2015 [NCT01422876] n=NA follow-up:	-	subjects with type 2 diabetes inadequately controlled on metformin	
empagliflozin vs linagliptin (monotherapy)			
Lewin , 2015 [NCT01422876] n=NA follow-up:	empagliflozin 25 mg/linagliptin 5 mg (n = 137), empagliflozin 10 mg/linagliptin 5 mg (n = 136), empagliflozin 25 mg (n = 135), empagliflozin 10 mg (n = 134) versus linagliptin 5 mg (n = 135) for 52 weeks		
empagliflozin vs placebo			
EMPA-REG OUTCOME , 2015 [NCT01131676] n=4687/2333 follow-up: 3.1 years (median)	10 mg or 25 mg of empagliflozin once daily versus placebo	patients with type 2 diabetes at high cardiovascular risk	Parallel groups double-blind 42 countries

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Trial	Treatments	Patients	Trials design and methods
EMPA-REG OUTCOME [NCT01131676] n=NA follow-up:	-	-	
Ferrannini , 2013 [NCT00789035] n=NA follow-up:	empagliflozin 5, 10 or 258201;mg once daily versus placebo	-	
EMPA-REG MONO (Roden) vs placebo , 2013 [NCT01177813] n=NA follow-up:	-	-	
Kadowaki , 2015 [NCT01193218] n=NA follow-up:	empagliflozin (5, 10, 25, or 50 mg) versus placebo	Japanese patients with type 2 diabetes	
Barnett , 2014 [NCT01164501] n=NA follow-up:	/ BI 10773 low dose (BI 10773 tablets once daily) 2/ BI 10773 high dose (BI 10773 tablets once daily) versus Placebo	Patients With Mild or Moderate Renal Impairment	
1245.29 ongoing [NCT02182830] n=NA follow-up:	Empagliflozin (starting dose 10mg; forced titration after 4 weeks 25mg dose) versus Placebo	Hypertensive Black/African American Patients With Type 2 Diabetes Mellitus and Hypertension	USA
empagliflozin vs placebo (add on MET+/-PIO)			
EMPA-REG PIO (Kovacs) , 2013 [NCT01210001] n=NA follow-up:	once daily empagliflozin 108201;mg (n8201;=8201;165), empagliflozin 258201;mg versus add-on to pioglitazone8201;8201;metformin	-	
empagliflozin vs placebo (add-on INS+/-MET)			
Rosenstock (1245.49) , 2014 [NCT01306214] n=NA follow-up: 18 weeks	once-daily empagliflozin 10 mg (n = 186), empagliflozin 25 mg (n = 189), versus placebo	Patients inadequately controlled on MDI insulin metformin	USA

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Trial	Treatments	Patients	Trials design and methods
empagliflozin vs placebo (add-on MET)			
Rosenstock , 2013 [NCT00749190] n=NA follow-up:	-	-	
Ross , 2015 [e2012-000905-53] n=NA follow-up:	empagliflozin 12.58201;mg twice daily (n8201;=8201;219), 258201;mg once daily (n8201;=8201;218), 58201;mg twice daily (n8201;=8201;219) or 108201;mg once daily (n8201;=8201;220), versus placebo	patients with type 2 diabetes inadequately controlled on metformin	
EMPA-REG MET (Haring) , 2014 [NCT01159600] n=NA follow-up:	empagliflozin 10 mg (n = 217), empagliflozin 25 mg (n = 213), versus placebo	Patients with HbA1c levels of 7% to 10% (53 to 86 mmol/mol) while receiving metformin (1,500 mg/day)	
empagliflozin vs placebo (add-on standard treatment)			
Araki , 2015 [NCT01368081] n=NA follow-up: 52 w	BI 10773 low dose (BI 10773 low dose tablet once daily) 2/ BI 10773 high dose (BI 10773 high dose tablet once daily) versus Metformin (Metformin tablets 500-2250 mg a day (twice or three times per day))	Japanese patients with type 2 diabetes mellitus	Japan
empagliflozin vs add-on linagliptin + MET			
1275.9 ongoing [NCT01734785] n=NA follow-up:	-	-	
empagliflozin + MET vs MET			
1276.1 (bitherapy MET) ongoing [NCT01719003] n=NA follow-up:	-	Treatment Naive Patients With Type 2 Diabetes	
empagliflozin vs placebo (add on MET+/-SU)			

continued...

Trial	Treatments	Patients	Trials design and methods
99050 <i>ongoing</i> [NCT01257334] n=NA follow-up:	BI 10773 10 mg, 25 mg administered once daily versus Placebo	Patients With Type 2 Diabetes Mellitus With Insufficient Glycaemic Control Despite Treatment With Metformin Alone or Metformin in Combination With a Sulfonylurea	Taiwan
empagliflozin vs Placebo (add-on INS)			
Rosenstock DOUBLON ??? , 2013 n=NA follow-up:	-	-	
EASE-2 <i>ongoing</i> [NCT02414958] n=NA follow-up:	-	-	
empagliflozin vs placebo add-on linagliptin			
1275.19 <i>ongoing</i> [NCT02453555] n=NA follow-up: 24 w	-	-	Japan

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More details and results :

- SGLT2 inhibitors for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q479>
- glucose lowering for cardiovascular prevention for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q576>
- glucose lowering for cardiovascular prevention for diabetes type 2 in meta-regression at <http://www.trialresultscenter.org/go-Q692>

References

Kadowaki, 2013:

Kadowaki T, Haneda M, Inagaki N et al. Empagliflozin monotherapy for 12 weeks improves glycemc control in Japanese patients with type 2 diabetes (T2DM) Diabetes 2013; 62: A297298.

Kadowaki , 2014:

Kadowaki T, Haneda M, Inagaki N, Terauchi Y, Taniguchi A, Koiwai K, Rattunde H, Woerle HJ, Broedl UC Empagliflozin monotherapy in Japanese patients with type 2 diabetes mellitus: a randomized, 12-week, double-blind, placebo-controlled, phase II trial. Adv Ther 2014;31:621-38 [24958326]

Ridderstrale, 2014:

Ridderstrle M, Svaerd R, Zeller C, Kim G, Woerle HJ, Broedl UC Rationale, design and baseline characteristics of a 4-year (208-week) phase III trial of empagliflozin, an SGLT2 inhibitor, versus glimepiride as add-on to metformin in patients with type 2 diabetes mellitus with insufficient glycaemic control. *Cardiovasc Diabetol* 2013;12:129 [24007456]

Ridderstrle M, Andersen KR, Zeller C, Kim G, Woerle HJ, Broedl UC Comparison of empagliflozin and glimepiride as add-on to metformin in patients with type 2 diabetes: a 104-week randomised, active-controlled, double-blind, phase 3 trial. *Lancet Diabetes Endocrinol* 2014;2:691-700 [24948511]

DeFronzo, 2015:

Lewin A, DeFronzo RA, Patel S, Liu D, Kaste R, Woerle HJ, Broedl UC Initial combination of empagliflozin and linagliptin in subjects with type 2 diabetes. *Diabetes Care* 2015;38:394-402 [25633662]

DeFronzo RA, Lewin A, Patel S, Liu D, Kaste R, Woerle HJ, Broedl UC Combination of empagliflozin and linagliptin as second-line therapy in subjects with type 2 diabetes inadequately controlled on metformin. *Diabetes Care* 2015;38:384-93 [25583754]

Lewin, 2015:

Lewin A, DeFronzo RA, Patel S, Liu D, Kaste R, Woerle HJ, Broedl UC Initial combination of empagliflozin and linagliptin in subjects with type 2 diabetes. *Diabetes Care* 2015;38:394-402 [25633662]

EMPA-REG OUTCOME, 2015:

Zinman B, Inzucchi SE, Lachin JM, Wanner C, Ferrari R, Fitchett D, Bluhmki E, Hantel S, Kempthorne-Rawson J, Newman J, Johansen OE, Woerle HJ, Broedl UC Rationale, design, and baseline characteristics of a randomized, placebo-controlled cardiovascular outcome trial of empagliflozin (EMPA-REG OUTCOME). *Cardiovasc Diabetol* 2014;13:102 [24943000]

Zinman B, Wanner C, Lachin JM, Fitchett D, Bluhmki E, Hantel S, Mattheus M, Devins T, Johansen OE, Woerle HJ, Broedl UC, Inzucchi SE Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes. *N Engl J Med* 2015 Sep 17;: [26378978] 10.1056/NEJMoa1504720

EMPA-REG OUTCOME, 0:

Ferrannini, 2013:

Ferrannini E, Seman L, Seewaldt-Becker E, Hantel S, Pinnetti S, Woerle HJ A Phase IIb, randomized, placebo-controlled study of the SGLT2 inhibitor empagliflozin in patients with type 2 diabetes. *Diabetes Obes Metab* 2013;15:721-8 [23398530] 10.1111/dom.12081

EMPA-REG MONO (Rodén) vs placebo, 2013:

Rodén M, Weng J, Eilbracht J, Delafont B, Kim G, Woerle HJ, Broedl UC Empagliflozin monotherapy with sitagliptin as an active comparator in patients with type 2 diabetes: a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Diabetes Endocrinol* 2013;1:208-19 [24622369] 10.1016/S2213-8587(13)70084-6

Kadowaki, 2015:

Kadowaki T, Haneda M, Inagaki N, Terauchi Y, Taniguchi A, Koiwai K, Rattunde H, Woerle HJ, Broedl UC Efficacy and safety of empagliflozin monotherapy for 52 weeks in Japanese patients with type 2 diabetes: a randomized, double-blind, parallel-group study. *Adv Ther* 2015;32:306-18 [25845768]

Barnett, 2014:

Barnett AH, Mithal A, Manassie J, Jones R, Rattunde H, Woerle HJ, Broedl UC Efficacy and safety of empagliflozin added to existing antidiabetes treatment in patients with type 2 diabetes and chronic kidney disease: a randomised, double-blind, placebo-controlled trial. *Lancet Diabetes Endocrinol* 2014;2:369-84 [24795251]

1245.29, 0:

ongoing trial NCT02182830

EMPA-REG PIO (Kovacs), 2013:

Kovacs CS, Seshiah V, Swallow R, Jones R, Rattunde H, Woerle HJ, Broedl UC Empagliflozin improves glycaemic and weight control as add-on therapy to

pioglitazone or pioglitazone plus metformin in patients with type 2 diabetes: a 24-week, randomized, placebo-controlled trial. *Diabetes Obes Metab* 2014;16:147-58 [23906415] [10.1111/dom.12188](https://doi.org/10.1111/dom.12188)

Rosenstock (1245.49), 2014:

Rosenstock J, Jelaska A, Frappin G, Salsali A, Kim G, Woerle HJ, Broedl UC Improved glucose control with weight loss, lower insulin doses, and no increased hypoglycemia with empagliflozin added to titrated multiple daily injections of insulin in obese inadequately controlled type 2 diabetes. *Diabetes Care* 2014;37:1815-23 [24929430]

Rosenstock, 2013:

Rosenstock J, Seman LJ, Jelaska A, Hantel S, Pinnetti S, Hach T, Woerle HJ Efficacy and safety of empagliflozin, a sodium glucose cotransporter 2 (SGLT2) inhibitor, as add-on to metformin in type 2 diabetes with mild hyperglycaemia. *Diabetes Obes Metab* 2013;15:1154-60 [23906374] [10.1111/dom.12185](https://doi.org/10.1111/dom.12185)

Ross, 2015:

Ross S, Thamer C, Cescutti J, Meinicke T, Woerle HJ, Broedl UC Efficacy and safety of empagliflozin twice daily versus once daily in patients with type 2 diabetes inadequately controlled on metformin: a 16-week, randomized, placebo-controlled trial. *Diabetes Obes Metab* 2015;17:699-702 [25827441]

EMPA-REG MET (Haring), 2014:

Hring HU, Merker L, Seewaldt-Becker E, Weimer M, Meinicke T, Broedl UC, Woerle HJ Empagliflozin as add-on to metformin in patients with type 2 diabetes: a 24-week, randomized, double-blind, placebo-controlled trial. *Diabetes Care* 2014;37:1650-9 [24722494]

Araki, 2015:

Araki E, Tanizawa Y, Tanaka Y, Taniguchi A, Koiwai K, Kim G, Salsali A, Woerle HJ, Broedl UC Long-term treatment with empagliflozin as add-on to oral antidiabetes therapy in Japanese patients with type 2 diabetes mellitus. *Diabetes Obes Metab* 2015;17:665-74 [25772548]

1275.9, 0:

ongoing trial NCT01734785

1276.1 (bitherapy MET), 0:

ongoing trial NCT01719003

99050, 0:

ongoing trial NCT01257334

Rosenstock DOUBLON ???, 2013:

Rosenstock J, Jelaska A, Wang F et al. Empagliflozin as add on to basal insulin for 78 weeks improves glycemic control with weight loss in insulin-treated type 2 diabetes (T2DM) *Can J Diabetes* 2013; 37: S32.

EASE-2, 0:

ongoing trial NCT02414958

1275.19, 0:

ongoing trial NCT02453555

Entry terms: BI 10773, BI10773, BI-10773, Jardiance,