

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 <i>ongoing</i> [NCT01734785] n=NA follow-up:	-	-	
empagliflozin + MET vs MET			
1276.1 (bitherapy MET) <i>ongoing</i> [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>

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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]

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1245.29, 0:

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1275.9, 0:

ongoing trial NCT01734785

1276.1 (bitherapy MET), 0:

ongoing trial NCT01719003

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EASE-2, 0:

ongoing trial NCT02414958

1275.19, 0:

ongoing trial NCT02453555

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