

# Clinical trials of empagliflozin

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## 1 diabetes type 2

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

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

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

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

## References

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**1275.9, 0:**

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**EASE-2, 0:**

ongoing trial NCT02414958

**1275.19, 0:**

ongoing trial NCT02453555

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