Empagliflozin lowers serum uric acid in chronic kidney disease: exploratory analyses from the EMPA-KIDNEY trial

Supplementary Material

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Supplementary Tables & Figures

Supplementary Table 1: Characteristics of participants at baseline in those taking uric acid lowering therapy or colchicine at randomisation

	Participants taking any uric-acid lowering therapy* or colchicine at baseline		
	Yes N=2350	**No** N=4259	**Overall** N=6609
DEMOGRAPHICS			
Age at randomisation (years)			
Mean (SD)	63.9 (13.5)	63.8 (14.0)	63.8 (13.9)
Sex			
Male	1817 (77.3)	2600 (61.0)	4417 (66.8)
Female	533 (22.7)	1659 (39.0)	2192 (33.2)
Race (all regions)			
White	1344 (57.2)	2515 (59.1)	3859 (58.4)
Black	78 (3.3)	184 (4.3)	262 (4.0)
Asian	902 (38.4)	1491 (35.0)	2393 (36.2)
Mixed	9 (0.4)	12 (0.3)	21 (0.3)
Other	17 (0.7)	57 (1.3)	74 (1.1)
PRIOR DISEASE			
Prior diabetes†	971 (41.3)	2069 (48.6)	3040 (46.0)
History of cardiovascular disease‡	660 (28.1)	1105 (25.9)	1765 (26.7)
History of heart failure	274 (11.7)	384 (9.0)	658 (10.0)
History of gout	1171 (49.8)	536 (12.6)	1707 (25.8)
CAUSE OF KIDNEY DISEASE			
Diabetic kidney disease	574 (24.4)	1483 (34.8)	2057 (31.1)
Hypertension/renovascular	552 (23.5)	893 (21.0)	1445 (21.9)
Glomerular	685 (29.1)	984 (23.1)	1669 (25.3)
Other/unknown	539 (22.9)	899 (21.1)	1438 (21.8)
CLINICAL MEASUREMENTS			
Blood pressure (mmHg)			
Mean systolic (SD)	135.3 (17.8)	137.2 (18.5)	136.5 (18.3)
Mean diastolic (SD)	78.3 (11.6)	77.9 (11.9)	78.1 (11.8)
Body mass index (kg/m^2)			
Mean (SD)	30.0 (6.9)	29.6 (6.7)	29.7 (6.8)
LABORATORY MEASUREMENTS			
Estimated GFR (mL/min/1.73m^2)			
Mean (SD)	35.9 (13.0)	38.1 (15.1)	37.3 (14.4)
<30	874 (37.2)	1408 (33.1)	2282 (34.5)
≥30 <45	1046 (44.5)	1882 (44.2)	2928 (44.3)
≥45	430 (18.3)	969 (22.8)	1399 (21.2)
Urinary albumin-to-creatinine ratio (mg/g)			
Geometric mean (95% CI)	242 (224-262)	212 (200-225)	222 (212-233)
Median (Q1-Q3)	372 (61-1095)	310 (43-1056)	329 (49-1069)
<30	436 (18.6)	892 (20.9)	1328 (20.1)
≥30 ≤300	648 (27.6)	1216 (28.6)	1864 (28.2)
>300	1266 (53.9)	2151 (50.5)	3417 (51.7)
Serum uric acid (µmol/L)§			

Mean (SD)	378.7 (100.0)	459.6 (110.2)	431.3 (113.5)
NT-proBNP (ng/L)			
Geometric mean (95% CI)	170 (160-180)	170 (163-177)	170 (164-176)
Median (Q1-Q3)	159 (65-437)	161 (71-409)	160 (69-419)
CONCOMITANT MEDICATION USE			
RAS inhibitor	2047 (87.1)	3581 (84.1)	5628 (85.2)
Any diuretic therapy	1129 (48.0)	1686 (39.6)	2815 (42.6)
Loop diuretic	782 (33.3)	965 (22.7)	1747 (26.4)
Thiazide diuretic	416 (17.7)	706 (16.6)	1122 (17.0)
Lipid-lowering therapy	1529 (65.1)	2849 (66.9)	4378 (66.2)
Any uric acid lowering/gout therapy	2350 (100.0)	-	2350 (35.6)
Xanthine oxidase inhibitor[‖]	2215 (94.3)	-	2215 (33.5)
Primary uricosuric agent[¶]	118 (5.0)	-	118 (1.8)
Colchicine	111 (4.7)	-	111 (1.7)
SMOKING & ALCOHOL			
Ever smoked tobacco regularly[#]	1087 (46.3)	1862 (43.7)	2949 (44.6)
Ever drunk alcohol regularly[Δ]	1060 (45.1)	1614 (37.9)	2674 (40.5)
5-YEAR RISK OF KIDNEY FAILURE (KFRE, %), median (Q1-Q3)	11.1 (3.6-29.7)	8.5 (2.7-28.1)	9.4 (2.9-28.9)

Figures are n (%) or mean (SD) or median (Q1-Q3). *Includes xanthine oxidase inhibitors (allopurinol, febuxostat, topiroxostat); primary uricosuric agents (benzbromarone, probenecid); and colchicine. [†]Defined as participant-reported history of diabetes of any type, use of glucose-lowering medication or baseline HbA1c ≥48 mmol/mol at randomisation visit. [‡]Defined as participant-reported history of myocardial infarction, heart failure, stroke, transient ischaemic attack, or peripheral arterial disease. [§]To convert uric acid to mg/dL, divide by 59.48 (431.3 μmol/L ≈ 7.2 mg/dL). [‖]Allopurinol, febuxostat or topiroxostat. [¶]Benzbromarone or probenecid. [#]Defined as for most days for at least 1 year. [Δ]Defined as at least 1 day a week for at least 1 year. Abbreviations: GFR = glomerular filtration rate; ACR = albumin-to-creatinine ratio; RAS = renin-angiotensin system.

Supplementary Table 2: Characteristics of participants at baseline in those reporting a history of gout at randomisation

	Self-reported history of gout at randomisation		
	Yes N=1707	**No** N=4902	**Overall** N=6609
DEMOGRAPHICS			
Age at randomisation (years)			
Mean (SD)	66.0 (12.1)	63.1 (14.3)	63.8 (13.9)
Sex			
Male	1329 (77.9)	3088 (63.0)	4417 (66.8)
Female	378 (22.1)	1814 (37.0)	2192 (33.2)
Race (all regions)			
White	1160 (68.0)	2699 (55.1)	3859 (58.4)
Black	82 (4.8)	180 (3.7)	262 (4.0)
Asian	436 (25.5)	1957 (39.9)	2393 (36.2)
Mixed	10 (0.6)	11 (0.2)	21 (0.3)
Other	19 (1.1)	55 (1.1)	74 (1.1)
PRIOR DISEASE			
Prior diabetes†	795 (46.6)	2245 (45.8)	3040 (46.0)
History of cardiovascular disease‡	535 (31.3)	1230 (25.1)	1765 (26.7)
History of heart failure	236 (13.8)	422 (8.6)	658 (10.0)
CAUSE OF KIDNEY DISEASE			
Diabetic kidney disease	485 (28.4)	1572 (32.1)	2057 (31.1)
Hypertension/renovascular	415 (24.3)	1030 (21.0)	1445 (21.9)
Glomerular	376 (22.0)	1293 (26.4)	1669 (25.3)
Other/unknown	431 (25.2)	1007 (20.5)	1438 (21.8)
CLINICAL MEASUREMENTS			
Blood pressure (mmHg)			
Mean systolic (SD)	136.5 (18.5)	136.5 (18.2)	136.5 (18.3)
Mean diastolic (SD)	77.4 (11.6)	78.3 (11.9)	78.1 (11.8)
Body mass index (kg/m^2)			
Mean (SD)	31.5 (7.0)	29.1 (6.6)	29.7 (6.8)
LABORATORY MEASUREMENTS			
Estimated GFR (mL/min/1.73m^2)			
Mean (SD)	34.4 (11.5)	38.3 (15.2)	37.3 (14.4)
<30	684 (40.1)	1598 (32.6)	2282 (34.5)
≥30 <45	775 (45.4)	2153 (43.9)	2928 (44.3)
≥45	248 (14.5)	1151 (23.5)	1399 (21.2)
Urinary albumin-to-creatinine ratio (mg/g)			
Geometric mean (95% CI)	188 (171-207)	235 (223-249)	222 (212-233)
Median (Q1-Q3)	275 (37-988)	346 (54-1094)	329 (49-1069)
<30	389 (22.8)	939 (19.2)	1328 (20.1)
≥30 ≤300	491 (28.8)	1373 (28.0)	1864 (28.2)
>300	827 (48.4)	2590 (52.8)	3417 (51.7)
Serum uric acid (µmol/L)§			
Mean (SD)	421.7 (121.3)	435.1 (110.2)	431.3 (113.5)
NT-proBNP (ng/L)			
Geometric mean (95% CI)	195 (182-209)	162 (155-168)	170 (164-176)
Median (Q1-Q3)	184 (78-491)	153 (67-396)	160 (69-419)
CONCOMITANT MEDICATION USE			

RAS inhibitor	1463 (85.7)	4165 (85.0)	5628 (85.2)
Any diuretic therapy	860 (50.4)	1955 (39.9)	2815 (42.6)
Loop diuretic	575 (33.7)	1172 (23.9)	1747 (26.4)
Thiazide diuretic	327 (19.2)	795 (16.2)	1122 (17.0)
Lipid-lowering therapy	1217 (71.3)	3161 (64.5)	4378 (66.2)
Any uric acid lowering/gout therapy	1171 (68.6)	1179 (24.1)	2350 (35.6)
Xanthine oxidase inhibitor[‖]	1125 (65.9)	1090 (22.2)	2215 (33.5)
Primary uricosuric agent[¶]	26 (1.5)	92 (1.9)	118 (1.8)
Colchicine	103 (6.0)	8 (0.2)	111 (1.7)
SMOKING & ALCOHOL			
Ever smoked tobacco regularly[#]	828 (48.5)	2121 (43.3)	2949 (44.6)
Ever drunk alcohol regularly[Δ]	852 (49.9)	1822 (37.2)	2674 (40.5)
5-YEAR RISK OF KIDNEY FAILURE (KFRE, %), median (Q1-Q3)	11.3 (3.9-30.6)	8.7 (2.7-28.0)	9.4 (2.9-28.9)

Figures are n (%) or mean (SD) or median (Q1-Q3). [†]Defined as participant-reported history of diabetes of any type, use of glucose-lowering medication or baseline HbA1c ≥48 mmol/mol at randomisation visit. [‡]Defined as participant-reported history of myocardial infarction, heart failure, stroke, transient ischaemic attack, or peripheral arterial disease. [§]To convert uric acid to mg/dL, divide by 59.48 (431.3 μmol/L ≈ 7.2 mg/dL). [‖]Allopurinol, febuxostat or topiroxostat. [¶]Benzbromarone or probenecid. [#]Defined as for most days for at least 1 year. [Δ]Defined as at least 1 day a week for at least 1 year. Abbreviations: GFR = glomerular filtration rate; ACR = albumin-to-creatinine ratio; RAS = renin-angiotensin system.

Supplementary Table 3: Proportion of the effect of empagliflozin on chronic eGFR slope explained by serum uric acid and other biomarkers at 2 months

Biomarkers	Absolute difference in chronic slope for empagliflozin vs placebo	Wald χ^2	% reduction in χ^2	Proportion of treatment effect explained (95% CI), %
None	1.36 (1.07, 1.66)	82.0	-	-
uACR	1.16 (0.87, 1.45)	61.0	25.6	15 (10,22)
Systolic blood pressure	1.28 (0.99, 1.58)	72.9	11.1	6 (3,11)
Diastolic blood pressure	1.35 (1.05, 1.64)	79.9	2.5	1 (0,4)
HbA1c	1.38 (1.08, 1.67)	83.3	-1.6	-1 (-3,1)
Uric acid	1.43 (1.13, 1.72)	88.7	-8.2	-4 (-9,-1)
uACR, systolic and diastolic blood pressure, HbA1c and uric acid	1.16 (0.87, 1.46)	61.3	25.2	15 (7,23)

Analyses restricted to 2586 participants with non-missing uric acid (and other biomarkers) at 2 months and a minimum of 2 eGFR measurements between 2 months and the final follow-up visit and therefore differ from previous publication (Staplin et al. Lancet Diabetes Endocrinol. 2024). Chronic slopes calculated for each individual participant using linear regression. The proportion of the treatment effect explained by 2-month biomarkers is estimated using the landmark method, adjusting a linear regression model with chronic slope as the dependent variable for 2 month values of biomarkers (categorised as approximate fifths). Analyses were additionally adjusted for baseline variables specified in the minimisation algorithm (age, sex, prior diabetes, eGFR, uACR and region). Confidence intervals for the proportion of treatment effect explained were constructed from bias-corrected and accelerated bootstrap intervals with 10000 replications. Replicating the analysis exploring proportion of treatment effect on the primary outcome and kidney disease progression outcome yielded consistent findings. Abbreviations: uACR = urinary albumin-to-creatinine ratio; HbA1c = glycated haemoglobin.

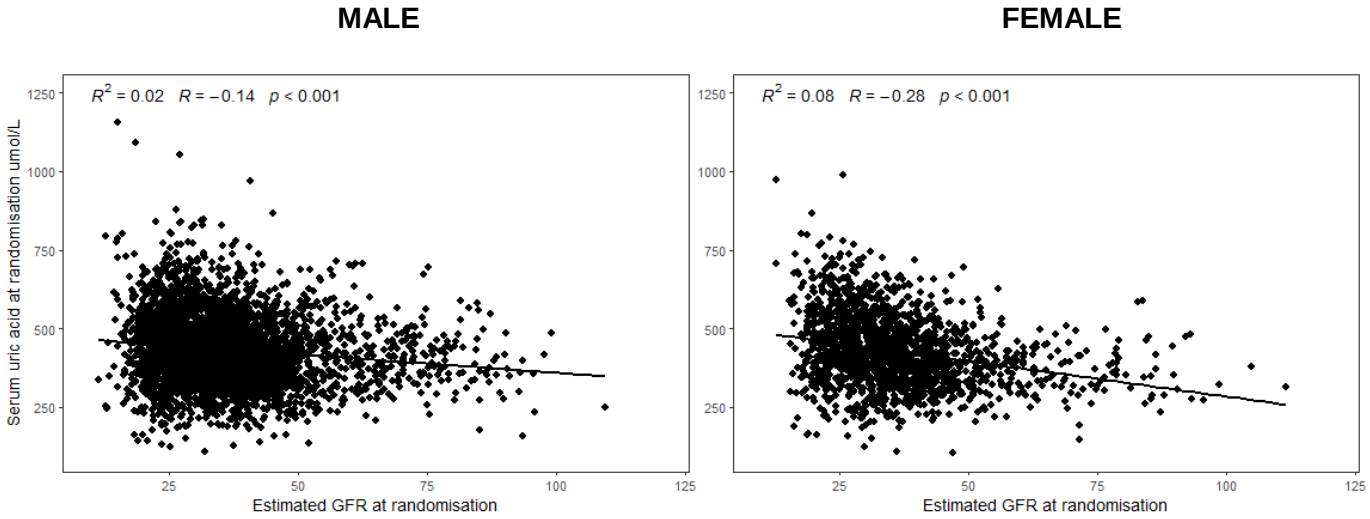
Supplementary Table 4: Summary of uric acid lowering effects in other large SGLT2 inhibitor trials

Trial	% with diabetes[1]	Mean baseline eGFR	Between group difference in uric acid, umol/L*	Time point at which between group difference in uric acid reported	Effects on gout events alone (where reported)
EMPA-REG OUTCOME[2]	100%	74	22.0	52 weeks	Time to first gout event: HR 0.81 (95% CI 0.56-1.16); 77 vs 47 events; 1.6 vs 2.0% (pooled empagliflozin vs placebo)
CANVAS[3]	100%	77	23.3	Study average (median follow-up 2.4 years); measured at every visit	Time to first gout event: HR 0.64 (95% CI 0.41-0.99); total 80 events; 2.0 vs 2.6% (canagliflozin vs placebo) Recurrent gout events: HR 0.54 (95% CI 0.38-0.76); total 125 events; 2.8 vs 4.3%
CREDENCE[4]	100%	56	13.1	Study average (median follow-up 2.6 years); measured at every visit	-
DAPA-HF[5]	45%	66	50.0	12 months	-
EMPEROR-Reduced[6]	50%	62	66.6	4 weeks†	Time to first gout event: HR 0.70 (95% CI 0.45-1.08); 36 vs 49 events; 1.9 vs 2.6% (empagliflozin vs placebo)
VERTIS-CV[7]	100%	76	22.0	Study average (median follow-up 3.0 years); measured at every visit	-
DAPA-CKD	68%	43	Not reported		-
EMPEROR-Preserved[8]	49%	61	59.5	4 weeks	-
DELIVER	50%	61	Not reported		-
EMPA-KIDNEY	46%	37	25.6	Study average (median follow-up 2.0 years); measured at 2 and 18 months	*See Table 2*

*Where reported in mg/dL, approximately converted to µmol/L by multiplying by 59.48. †Difference persisted to week 100 but between group difference not quantified. eGFR = estimated glomerular filtration rate, HR = hazard ratio, CI = confidence interval.

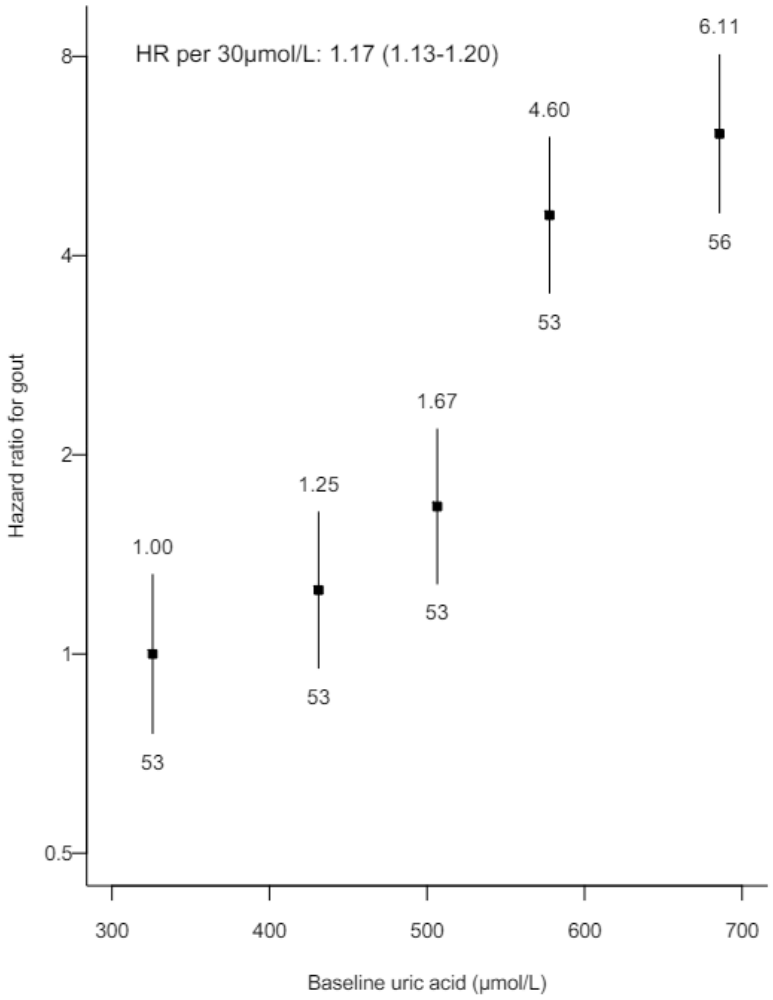
[1] Characteristics for all presented trials including proportion with diabetes and mean eGFR at baseline are summarised in: Nuffield Department of Population Health & SGLT2 inhibitor Meta-Analysis Cardio-Renal Trialists' Consortium. 2022. Lancet.
[2] Ferreira JP et al. 2021. Diabetes Obes Metab.
[3] Li J et al. 2020. Kidney International. & Li J et al. 2019. Lancet Rheumatol.
[4] Doi Y et al. 2023. Diabetes Obes Metab.
[5] McDowell K et al. 2022. Eur J Heart Fail.
[6] Doehner W et al. 2022. Eur Heart J.
[7] Segar MW et al. 2022. Diabetes Obes Metab.
[8] Green J et al. 2023. Metabolism.

Supplementary Figure 1: Correlation between serum uric acid & estimated glomerular filtration rate at randomisation by sex



R = Spearman correlation coefficient. To convert uric acid to mg/dL, divide by 59.48.

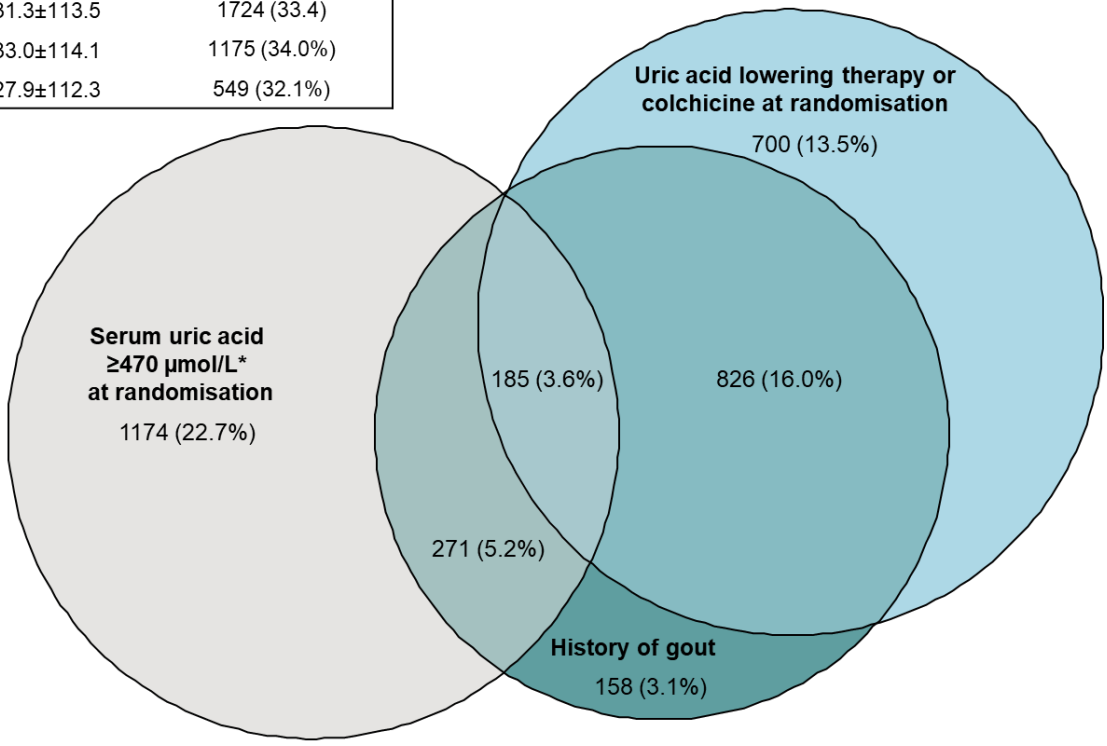
Supplementary Figure 2: Relationship between baseline serum uric acid and first gout events in those allocated to placebo



Hazard ratio for the time to first gout event in 2590 participants allocated to placebo who had a baseline measurement of serum uric acid (µmol/L). Baseline uric acid was categorised into fifths to ensure approximately equal numbers of gout events in each category. Cox regression model adjusted for the covariates used in the minimisation algorithm (categories of age, sex, diabetes, estimated glomerular filtration rate, urinary albumin-to-creatinine ratio and region). To convert uric acid to mg/dL, divide by 59.48 (500 µmol/L ≈ 8.4 mg/dL).

Supplementary Figure 3: Relationship between history of previous gout; uric acid lowering therapy or colchicine; and hyperuricaemia at randomisation

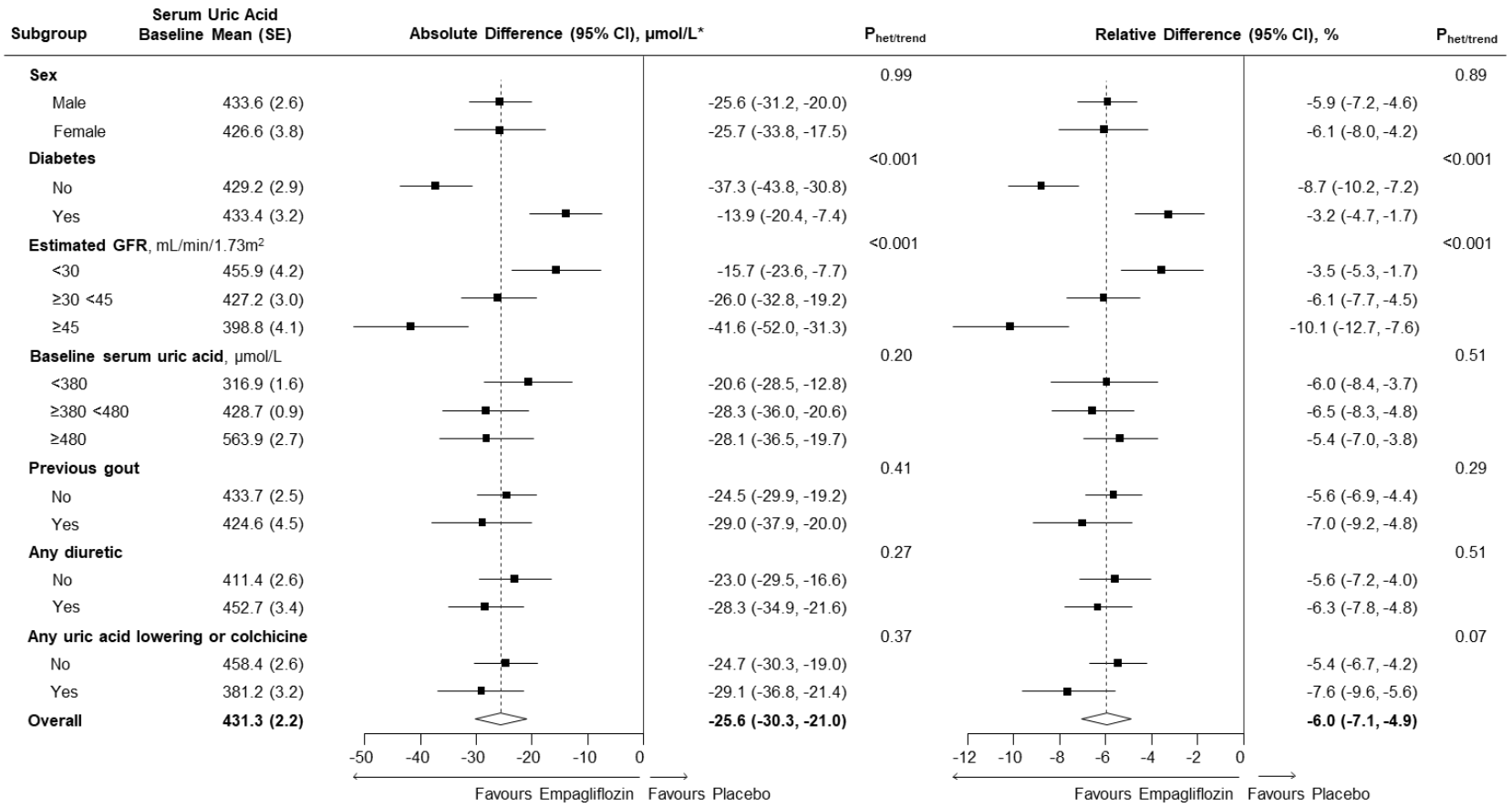
	Serum uric acid at randomisation (μmol/L)	
	Mean±SD	**N(%) ≥470***
Overall	431.3±113.5	1724 (33.4)
Male	433.0±114.1	1175 (34.0%)
Female	427.9±112.3	549 (32.1%)



Participants (with baseline uric acid measurement) not fulfilling any of these criteria 1854 (35.9%)

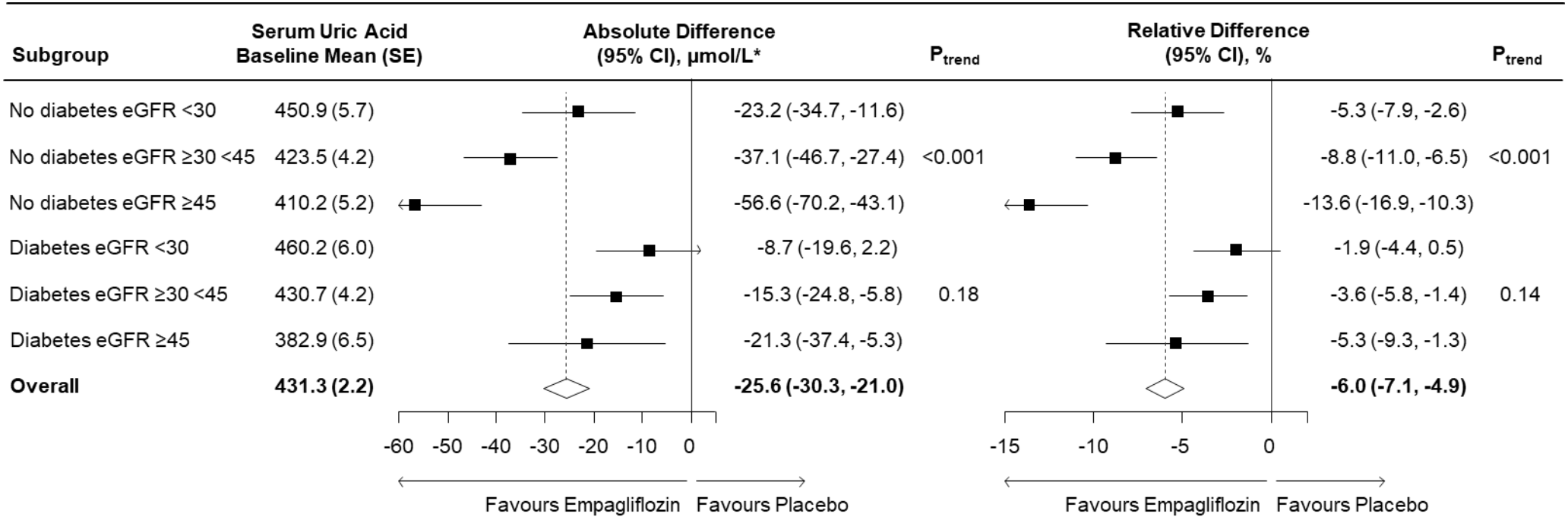
Includes only participants with uric acid measured at randomisation, n=5168 (missing n=1441). Uric-acid lowering therapy includes xanthine oxidase inhibitors and primary uricosuric drugs (see Methods). *Corresponds to the top third of those with uric acid measured at randomisation, used in subgroup categorisation for time-to event analyses (Figure 3). To convert uric acid to mg/dL, divide by 59.48 (431 μmol/L ≈ 7.2 mg/dL; 470 μmol/L ≈ 7.9 mg/dL).

Supplementary Figure 4: Absolute and relative effects of empagliflozin versus placebo on serum uric acid in subgroups defined by baseline characteristics



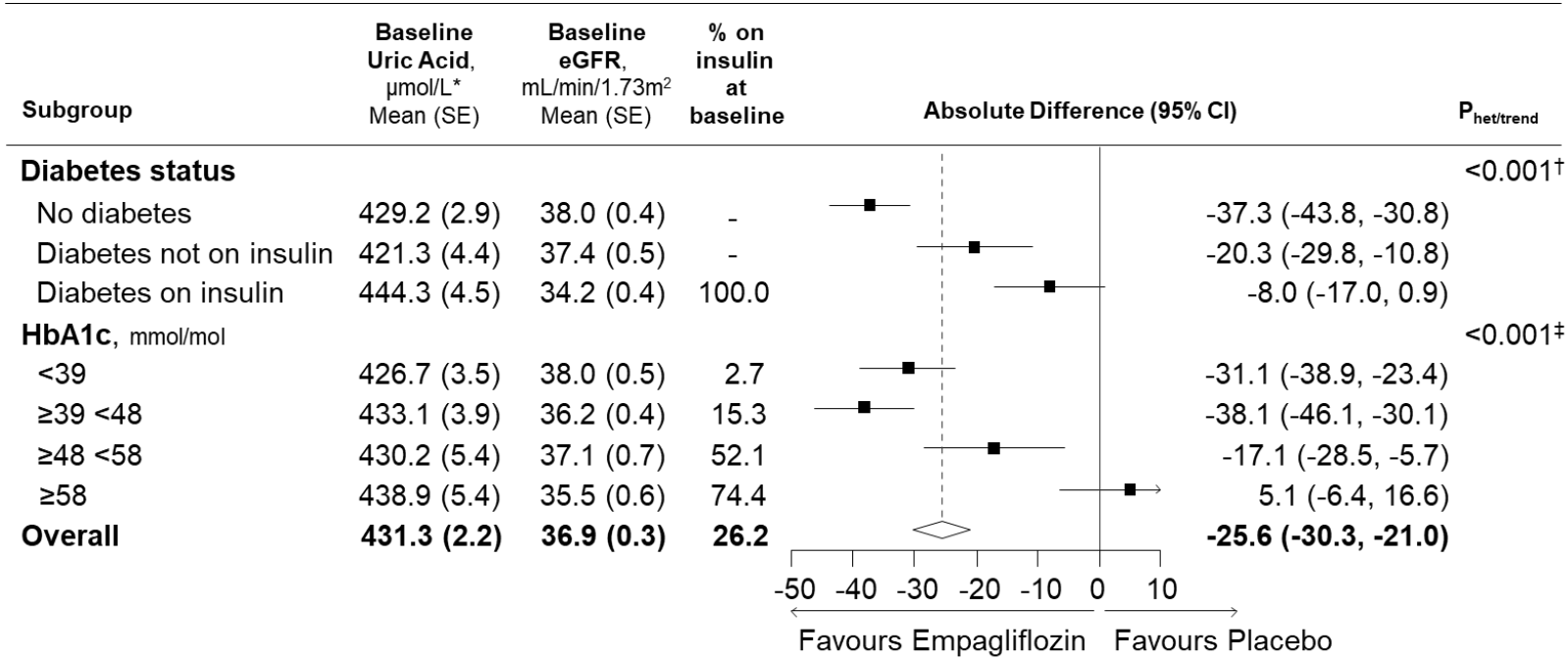
*To convert uric acid to mg/dL, divide by 59.48 (380 µmol/L ≈ 6.4 mg/dL; 480 µmol/L ≈ 8.1 mg/dL). Analysis required participants to have at least one measurement of uric acid during follow-up at 2 and/or 18 months (n=2691 participants). Absolute differences in study-average uric acid (empagliflozin minus placebo) are derived from a repeated measures mixed model (MMRM) adjusted for baseline serum uric acid (in continuous form), baseline-by-time interaction, the covariates used in the minimisation algorithm (categories of age, sex, diabetes, estimated glomerular filtration rate, urinary albumin-to-creatinine ratio and region) fixed categorical effects of time, treatment allocation and treatment-by-time interaction, and weighted in proportion to the amount of time between follow-up visits. Interaction terms are included in the MMRM models to assess for heterogeneity (sex, diabetes, previous gout, any diuretic therapy) between or trend (estimated GFR, serum uric acid) across subgroup-specific means and standard errors. Uric-acid lowering therapy includes xanthine oxidase inhibitors and primary uricosuric drugs (see Methods). GFR = glomerular filtration rate. *The figure reflects baseline use of diuretics (and other characteristics) however it is relevant that among those participants in the full trial cohort who were not taking a loop diuretic at randomization, 159 of 2453 (6.5%) in the empagliflozin group compared with 212 of 2409 (8.8%) in the placebo group started such medication during follow-up, representing a 26% lower likelihood of a new loop diuretic prescription among the empagliflozin group (risk ratio 0.74, 95% CI, 0.60 to 0.90). Missing baseline uric acid (4/2691 participants) was imputed with the baseline mean and so participants are included in the middle subgroup category ≥380 <480 µmol/L.

Supplementary Figure 5: Effects of empagliflozin versus placebo on serum uric acid by diabetes status and eGFR



*To convert uric acid to mg/dL, divide by 59.48 (25.6 µmol/L ≈ 0.4 mg/dL). Analysis required participants to have at least one measurement of uric acid during follow-up at 2 and/or 18 months (n=2691 participants). Absolute differences in study-average uric acid (empagliflozin minus placebo) are derived from a repeated measures mixed model (MMRM) adjusted for baseline serum uric acid (in continuous form), baseline-by-time interaction, the covariates used in the minimisation algorithm (categories of age, sex, diabetes, estimated glomerular filtration rate, urinary albumin-to-creatinine ratio and region) fixed categorical effects of time, treatment allocation and treatment-by-time interaction, and weighted in proportion to the amount of time between follow-up visits. There was evidence that the trend in uric acid lowering effects across eGFR categories differed by diabetes status (likelihood ratio test P<0.001 comparing models without and with the additional interaction terms diabetes*eGFR*treatment and diabetes*eGFR *treatment*time with the categorical eGFR variable in continuous form), therefore interaction terms are included in the MMRM models to assess for trend across subgroup-specific means and standard errors in estimated GFR categories in participants with and without diabetes separately. eGFR = estimated glomerular filtration rate. Missing baseline uric acid (4/2691 participants) was imputed with the baseline mean.

Supplementary Figure 6: Further exploration of differential effects of empagliflozin on serum uric acid in participants with and without diabetes



*To convert uric acid to mg/dL, divide by 59.48 (431.3 µmol/L ≈ 7.2 mg/dL; 25.6 µmol/L ≈ 0.4 mg/dL). Analysis required participants to have at least one measurement of uric acid during follow-up at 2 and/or 18 months (n=2691 participants). Absolute differences in study-average uric acid (empagliflozin minus placebo) are derived from a repeated measures mixed model (MMRM) adjusted for baseline serum uric acid (in continuous form), baseline-by-time interaction, the covariates used in the minimisation algorithm (categories of age, sex, estimated glomerular filtration rate, urinary albumin-to-creatinine ratio and region) fixed categorical effects of time, treatment allocation and treatment-by-time interaction, and weighted in proportion to the amount of time between follow-up visits. Interaction terms are included in the MMRM models to assess for †heterogeneity or ‡trend across subgroup-specific means and standard errors. Participants with missing HbA1c (32/2691, 1.2%) are included in the ≥39 <48 mmol/mol category containing the mean value of 46 mmol/mol. eGFR = estimated glomerular filtration rate; HbA1c = glycated haemoglobin. Missing baseline uric acid (4/2691 participants) was imputed with the baseline mean.