

Supplementary Material

Supplementary Tables

Supplementary Table S1. Change in SGLT-2i and GLP-1RA use during the study (FAS)

SGLT-2i				
and GLP-1RA use at baseline	Any combined SGLT-2i and GLP-1RA use on-treatment	Finerenone (<i>n</i> = 6498)	Placebo (<i>n</i> = 6492)	Total (<i>N</i> = 12 990)
Yes	Yes	86 (1.3)	81 (1.2)	167 (1.3)
	No	0 (0)	0 (0)	0 (0)
No	Yes	224 (3.4)	239 (3.7)	463 (3.6)
	No	6188 (95.2)	6172 (95.1)	12 360 (95.2)

Data presented are *n* (%). Medications taken on or before day of randomisation and ended after randomisation were considered as baseline use. Medications were considered on-treatment use if taken in the period from randomisation up until the minimum of end-of-study visit, last contact date and 30 days after end of treatment.

FAS, full analysis set; GLP-1RA, glucagon-like peptide-1 receptor agonist; SGLT-2i, sodium-glucose cotransporter-2 inhibitor.

Supplementary Table S2. Type of combined SGLT-2i and GLP-1RA administered throughout the study (FAS)

GLP-1RA	SGLT-2i	Total (<i>N</i> = 12 990)
Number of participants with frequent (<i>n</i> ≥ 5) combined use of SGLT-2i and GLP-1RA at baseline, <i>n</i> (%)		
LIRAGLUTIDE	EMPAGLIFLOZIN	53 (0.4)
	DAPAGLIFLOZIN	33 (0.3)
DULAGLUTIDE	EMPAGLIFLOZIN	20 (0.2)
EXENATIDE	DAPAGLIFLOZIN	17 (0.1)
LIRAGLUTIDE	CANAGLIFLOZIN	14 (0.1)
EXENATIDE	EMPAGLIFLOZIN	9 (<0.1)
DULAGLUTIDE	CANAGLIFLOZIN	6 (<0.1)
	DAPAGLIFLOZIN	6 (<0.1)
Number of participants with frequent (<i>n</i> ≥ 5) combined use of SGLT-2i and GLP-1RA on-treatment, <i>n</i> (%)		
LIRAGLUTIDE	EMPAGLIFLOZIN	208 (1.6)
DULAGLUTIDE	EMPAGLIFLOZIN	127 (1.0)
LIRAGLUTIDE	DAPAGLIFLOZIN	118 (0.9)
SEMAGLUTIDE	EMPAGLIFLOZIN	75 (0.6)
DULAGLUTIDE	DAPAGLIFLOZIN	70 (0.5)
LIRAGLUTIDE	CANAGLIFLOZIN	43 (0.3)
EXENATIDE	EMPAGLIFLOZIN	42 (0.3)
	DAPAGLIFLOZIN	32 (0.2)
DULAGLUTIDE	CANAGLIFLOZIN	31 (0.2)
SEMAGLUTIDE	DAPAGLIFLOZIN	24 (0.2)
	CANAGLIFLOZIN	21 (0.2)
EXENATIDE	CANAGLIFLOZIN	12 (<0.1)
LIXISENATIDE	DAPAGLIFLOZIN	10 (<0.1)
LIRAGLUTIDE	IPRAGLIFLOZIN L-PROLINE	9 (<0.1)

GLP-1RA	SGLT-2i	Total (N = 12 990)
LIXISENATIDE	EMPAGLIFLOZIN	8 (<0.1)
LIRAGLUTIDE	LUSEOGLIFLOZIN	7 (<0.1)

Medications taken on or before day of randomisation and ended after randomisation were considered as baseline use. Medications were considered on-treatment use if taken in the period from randomisation up until the minimum of end-of-study visit, last contact date and 30 days after end of treatment. Multiple combinations per subject were possible in cases where a patient took more than one SGLT-2i or GLP-1RA.

FAS, full analysis set; GLP-1RA, glucagon-like peptide-1 receptor agonist; SGLT-2i, sodium-glucose cotransporter-2 inhibitor.

Supplementary Table S3. Baseline demographic and clinical characteristics by concomitant SGLT-2i and/or GLP-1RA use at baseline (FAS)

	Combined SGLT-2i and GLP-1RA use (<i>n</i> = 167)		No SGLT-2i or GLP-1RA use (<i>n</i> = 11 341)		SGLT-2i use only (<i>n</i> = 706)		GLP-1RA use only (<i>n</i> = 776)	
Characteristic	Finerenone (<i>n</i> = 86)	Placebo (<i>n</i> = 81)	Finerenone (<i>n</i> = 5651)	Placebo (<i>n</i> = 5690)	Finerenone (<i>n</i> = 350)	Placebo (<i>n</i> = 356)	Finerenone (<i>n</i> = 411)	Placebo (<i>n</i> = 365)
Age, years, mean (SD)	61.34 (9.60)	61.25 (9.97)	65.07 (9.35)	65.14 (9.67)	61.94 (9.72)	61.78 (9.52)	62.91 (8.59)	63.61 (8.95)
Sex, male, <i>n</i> (%)	61 (70.9)	64 (79.0)	3835 (67.9)	4005 (70.4)	269 (76.9)	274 (77.0)	298 (72.5)	252 (69.0)
Race, <i>n</i> (%)								
White	68 (79.1)	65 (80.2)	3809 (67.4)	3829 (67.3)	257 (73.4)	254 (71.3)	315 (76.6)	272 (74.5)
Black/African American	1 (1.2)	4 (4.9)	229 (4.1)	234 (4.1)	3 (0.9)	11 (3.1)	18 (4.4)	20 (5.5)
Asian	15 (17.4)	10 (12.3)	1258 (22.3)	1295 (22.8)	76 (21.7)	81 (22.8)	64 (15.6)	61 (16.7)
Duration of diabetes, years, mean (SD)	15.71 (7.89)	16.93 (7.64)	15.30 (8.77)	15.28 (8.75)	16.13 (8.56)	14.69 (7.64)	16.78 (8.39)	17.15 (8.00)

	Combined SGLT-2i and GLP-1RA use (<i>n</i> = 167)		No SGLT-2i or GLP-1RA use (<i>n</i> = 11 341)		SGLT-2i use only (<i>n</i> = 706)		GLP-1RA use only (<i>n</i> = 776)	
Characteristic	Finerenone (<i>n</i> = 86)	Placebo (<i>n</i> = 81)	Finerenone (<i>n</i> = 5651)	Placebo (<i>n</i> = 5690)	Finerenone (<i>n</i> = 350)	Placebo (<i>n</i> = 356)	Finerenone (<i>n</i> = 411)	Placebo (<i>n</i> = 365)
HbA1c, %, mean (SD)	7.86 (1.15)	7.82 (1.19)	7.68 (1.38)	7.66 (1.37)	7.95 (1.23)	8.01 (1.24)	7.82 (1.25)	7.77 (1.21)
BMI, kg/m ² , mean (SD)	34.69 (6.64)	33.85 (6.02)	31.00 (5.93)	31.04 (5.94)	32.31 (6.11)	31.95 (5.64)	34.35 (6.19)	33.86 (5.73)
Waist circumference, cm, mean (SD)	116.90 (14.02)	115.32 (14.98)	106.03 (14.86)	106.45 (14.98)	110.15 (14.6)	109.89 (14.69)	115.37 (15.98)	113.25 (14.60)
Systolic blood pressure, mm Hg, mean (SD)	133.43 (14.84)	133.45 (13.92)	137.09 (14.08)	136.95 (14.22)	133.17 (14.85)	133.32 (13.97)	136.21 (13.99)	137.28 (14.66)
Serum potassium, mmol/l, mean (SD)	4.27 (0.41)	4.35 (0.37)	4.36 (0.44)	4.36 (0.45)	4.28 (0.43)	4.30 (0.42)	4.30 (0.42)	4.31 (0.44)
eGFR, ml/min/1.73 m ² , mean (SD)	66.97 (23.15)	62.69 (18.40)	56.75 (21.45)	57.07 (21.72)	66.81 (20.74)	66.32 (21.50)	57.97 (21.70)	56.85 (21.26)

	Combined SGLT-2i and GLP-1RA use (<i>n</i> = 167)		No SGLT-2i or GLP-1RA use (<i>n</i> = 11 341)		SGLT-2i use only (<i>n</i> = 706)		GLP-1RA use only (<i>n</i> = 776)	
Characteristic	Finerenone (<i>n</i> = 86)	Placebo (<i>n</i> = 81)	Finerenone (<i>n</i> = 5651)	Placebo (<i>n</i> = 5690)	Finerenone (<i>n</i> = 350)	Placebo (<i>n</i> = 356)	Finerenone (<i>n</i> = 411)	Placebo (<i>n</i> = 365)
eGFR, ml/min/1.73 m ² , <i>n</i> (%)								
<25	0 (0)	0 (0)	78 (1.4)	77 (1.4)	0 (0)	0 (0)	3 (0.7)	4 (1.1)
25–<45	19 (22.1)	11 (13.6)	1906 (33.7)	1912 (33.6)	53 (15.1)	59 (16.6)	134 (32.6)	130 (35.6)
45–<60	14 (16.3)	31 (38.3)	1491 (26.4)	1491 (26.2)	94 (26.9)	100 (28.1)	112 (27.3)	93 (25.5)
≥60	53 (61.6)	39 (48.1)	2175 (38.5)	2208 (38.8)	203 (58.0)	197 (55.3)	162 (39.4)	138 (37.8)
UACR, mg/g, median, IQR (Q1–Q3)	413.31	460.68	524.81	521.27	449.57	445.24	463.36	521.35
	(97.85–	(207.41–	(200.90–	(203.29–	(190.47–	(181.60–	(172.00–	(177.69–
	870.42)	903.59)	1157.50)	1183.61)	972.69)	949.42)	974.82)	1169.25)
UACR, mg/g, <i>n</i> (%)								
<30	2 (2.3)	0 (0)	103 (1.8)	96 (1.7)	5 (1.4)	9 (2.5)	10 (2.4)	5 (1.4)

	Combined SGLT-2i and GLP-1RA use (<i>n</i> = 167)		No SGLT-2i or GLP-1RA use (<i>n</i> = 11 341)		SGLT-2i use only (<i>n</i> = 706)		GLP-1RA use only (<i>n</i> = 776)	
Characteristic	Finerenone (<i>n</i> = 86)	Placebo (<i>n</i> = 81)	Finerenone (<i>n</i> = 5651)	Placebo (<i>n</i> = 5690)	Finerenone (<i>n</i> = 350)	Placebo (<i>n</i> = 356)	Finerenone (<i>n</i> = 411)	Placebo (<i>n</i> = 365)
30–<300	32 (37.2)	26 (32.1)	1786 (31.6)	1759 (30.9)	109 (31.1)	114 (32.0)	139 (33.8)	116 (31.8)
≥300	52 (60.5)	55 (67.9)	3760 (66.5)	3832 (67.3)	236 (67.4)	233 (65.4)	262 (63.7)	244 (66.8)
Current smoker, <i>n</i> (%)	13 (15.1)	12 (14.8)	915 (16.2)	900 (15.8)	67 (19.1)	70 (19.7)	64 (15.6)	41 (11.2)
Heart rate, bpm, mean (SD)	77.85 (9.95)	77.98 (11.81)	72.72 (11.30)	72.55 (11.39)	73.75 (11.57)	74.59 (11.80)	77.61 (11.94)	76.73 (10.87)
hs-CRP, mg/l, median, IQR (Q1–Q3)	2.51 (1.21, 5.11)	2.01 (0.99, 4.59)	2.21 (0.94, 5.24)	2.21 (0.95, 5.10)	2.22 (1.06, 4.78)	2.28 (1.08, 4.74)	2.12 (0.84, 4.85)	2.45 (1.01, 5.55)
History of hyperkalaemia	1 (1.2)	1 (1.2)	93 (1.6)	95 (1.7)	7 (2.0)	3 (0.8)	11 (2.7)	13 (3.6)
Medication use at baseline, <i>n</i> (%) ^a								

	Combined SGLT-2i and GLP-1RA use (<i>n</i> = 167)		No SGLT-2i or GLP-1RA use (<i>n</i> = 11 341)		SGLT-2i use only (<i>n</i> = 706)		GLP-1RA use only (<i>n</i> = 776)	
Characteristic	Finerenone (<i>n</i> = 86)	Placebo (<i>n</i> = 81)	Finerenone (<i>n</i> = 5651)	Placebo (<i>n</i> = 5690)	Finerenone (<i>n</i> = 350)	Placebo (<i>n</i> = 356)	Finerenone (<i>n</i> = 411)	Placebo (<i>n</i> = 365)
RAS inhibitors (ACEis or ARBs)	85 (98.8)	81 (100.0)	5641 (99.8)	5680 (99.8)	350 (100.0)	355 (99.7)	411 (100.0)	364 (99.7)
Beta blockers	42 (48.8)	46 (56.8)	2793 (49.4)	2851 (50.1)	173 (49.4)	170 (47.8)	224 (54.5)	200 (54.8)
Diuretics	43 (50.0)	44 (54.3)	2849 (50.4)	2938 (51.6)	180 (51.4)	170 (47.8)	246 (59.9)	231 (63.3)
Statins	72 (83.7)	76 (93.8)	3945 (69.8)	4073 (71.6)	291 (83.1)	297 (83.4)	343 (83.5)	290 (79.5)
Potassium-lowering agents	NR	NR	85 (1.5)	81 (1.4)	5 (1.4)	2 (0.6)	4 (1.0)	5 (1.4)
Potassium supplements	4 (4.7)	3 (3.7)	161 (2.8)	156 (2.7)	6 (1.7)	11 (3.1)	25 (6.1)	19 (5.2)
Other glucose-lowering agents, <i>n</i> (%)								

	Combined SGLT-2i and GLP-1RA use (n = 167)		No SGLT-2i or GLP-1RA use (n = 11 341)		SGLT-2i use only (n = 706)		GLP-1RA use only (n = 776)	
Characteristic	Finerenone (n = 86)	Placebo (n = 81)	Finerenone (n = 5651)	Placebo (n = 5690)	Finerenone (n = 350)	Placebo (n = 356)	Finerenone (n = 411)	Placebo (n = 365)
Insulin and analogues	58 (67.4)	56 (69.1)	3316 (58.7)	3282 (57.7)	204 (58.3)	195 (54.8)	280 (68.1)	229 (62.7)
DPP-4 inhibitors	5 (5.8)	2 (2.5)	1491 (26.4)	1470 (25.8)	132 (37.7)	116 (32.6)	18 (4.4)	21 (5.8)
Sulfonamides	16 (18.6)	13 (16.0)	1475 (26.1)	1501 (26.4)	104 (29.7)	85 (23.9)	91 (22.1)	93 (25.5)
Biguanides	68 (79.1)	64 (79.0)	3159 (55.9)	3171 (55.7)	283 (80.9)	275 (77.2)	291 (70.8)	228 (62.5)
Alpha glucosidase inhibitors	3 (3.5)	0 (0)	281 (5.0)	310 (5.4)	22 (6.3)	10 (2.8)	16 (3.9)	10 (2.7)
Meglitinides	3 (3.5)	4 (4.9)	232 (4.1)	229 (4.0)	13 (3.7)	9 (2.5)	24 (5.8)	15 (4.1)
Thiazolidinediones	6 (7.0)	6 (7.4)	215 (3.8)	197 (3.5)	27 (7.7)	19 (5.3)	19 (4.6)	26 (7.1)

Patient demographics were conducted on the FAS, which included all 12 990 randomised participants.

^aMultiple drug groups per drug were possible. Therefore, the same drug could be counted in more than one category for the same subject. Medications taken on or before day of randomisation and ended after randomisation are included in this table.

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index; bpm, beats per minute; DDP-4, dipeptidyl peptidase-4 inhibitor; eGFR, estimated glomerular filtration rate; FAS, full analysis set; GLP-1RA, glucagon-like peptide-1 receptor agonist; HbA1c, haemoglobin A1C; hs-CRP, high-sensitivity C-reactive protein; IQR, interquartile range; Q, quartile; SD, standard deviation; SGLT-2i, sodium-glucose cotransporter-2 inhibitor; UACR, urine albumin-to-creatinine ratio.

Supplementary Table S4. SGLT-2i and/or GLP-1RA use at baseline according to region (FAS)

Region, <i>n</i> (%)	Combined SGLT-2i and GLP-1RA use (<i>n</i> = 167)	No SGLT-2i or GLP-1RA use (<i>n</i> = 11 341)	SGLT-2i use only (<i>n</i> = 706)	GLP-1RA use only (<i>n</i> = 776)
Western Europe	57 (34.1)	2161 (19.1)	187 (26.5)	331 (42.7)
Eastern Europe	9 (5.4)	2951 (26.0)	98 (13.9)	68 (8.8)
North America	34 (20.4)	1757 (15.5)	113 (16.0)	145 (18.7)
Asia	57 (34.1)	2720 (24.0)	206 (29.2)	187 (24.1)
Latin America	5 (3.0)	1341 (11.8)	64 (9.1)	24 (3.1)
Other ^a	5 (3.0)	411 (3.6)	38 (5.4)	21 (2.7)

Patient demographics were conducted on the FAS, which included all 12 990 randomised participants.

^aOther regions included New Zealand, South Africa and Australia.

FAS, full analysis set; GLP-1RA, glucagon-like peptide-1 receptor agonist; SGLT-2i, sodium-glucose cotransporter-2 inhibitor.

Supplementary Table S5. Treatment-emergent AEs affecting ≥5% of participants in any treatment group by concomitant SGLT-2i and/or GLP-1RA use at baseline (SAS)

Characteristic, <i>n</i> (%)	Combined SGLT-2i and							
	GLP-1RA use		No SGLT-2i or GLP-1RA		GLP-1RA use only		SGLT-2i use only	
	<i>(n</i> = 167)		use (<i>n</i> = 11 319)		<i>(n</i> = 771)		<i>(n</i> = 706)	
	Finerenone	Placebo	Finerenone	Placebo	Finerenone	Placebo	Finerenone	Placebo
	<i>(n</i> = 86)	<i>(n</i> = 81)	<i>(n</i> = 5643)	<i>(n</i> = 5676)	<i>(n</i> = 410)	<i>(n</i> = 361)	<i>(n</i> = 350)	<i>(n</i> = 356)
Abdominal pain	6 (7.0)	2 (2.5)	89 (1.6)	113 (2.0)	9 (2.2)	6 (1.7)	8 (2.3)	7 (2.0)
Acute kidney injury	1 (1.2)	3 (3.7)	189 (3.3)	200 (3.5)	26 (6.3)	19 (5.3)	4 (1.1)	12 (3.4)
Anaemia	3 (3.5)	0 (0)	378 (6.7)	358 (6.3)	33 (8.0)	24 (6.6)	11 (3.1)	15 (4.2)
Arthralgia	5 (5.8)	6 (7.4)	411 (7.3)	373 (6.6)	47 (11.5)	39 (10.8)	33 (9.4)	38 (10.7)
Back pain	9 (10.5)	4 (4.9)	346 (6.1)	365 (6.4)	43 (10.5)	35 (9.7)	35 (10.0)	23 (6.5)
Benign prostatic hyperplasia	5 (5.8)	1 (1.2)	130 (2.3)	138 (2.4)	13 (3.2)	9 (2.5)	11 (3.1)	4 (1.1)
Bronchitis	2 (2.3)	2 (2.5)	284 (5.0)	291 (5.1)	20 (4.9)	18 (5.0)	16 (4.6)	17 (4.8)

Characteristic, <i>n</i> (%)	Combined SGLT-2i and							
	GLP-1RA use		No SGLT-2i or GLP-1RA		GLP-1RA use only		SGLT-2i use only	
	<i>(n</i> = 167)		use (<i>n</i> = 11 319)		<i>(n</i> = 771)		<i>(n</i> = 706)	
	Finerenone	Placebo	Finerenone	Placebo	Finerenone	Placebo	Finerenone	Placebo
	<i>(n</i> = 86)	<i>(n</i> = 81)	<i>(n</i> = 5643)	<i>(n</i> = 5676)	<i>(n</i> = 410)	<i>(n</i> = 361)	<i>(n</i> = 350)	<i>(n</i> = 356)
Cataract	2 (2.3)	6 (7.4)	238 (4.2)	237 (4.2)	21 (5.1)	23 (6.4)	14 (4.0)	19 (5.3)
Cellulitis	3 (3.5)	2 (2.5)	136 (2.4)	118 (2.1)	16 (3.9)	10 (2.8)	19 (5.4)	14 (3.9)
Chest pain	11 (12.8)	2 (2.5)	132 (2.3)	154 (2.7)	17 (4.1)	17 (4.7)	9 (2.6)	17 (4.8)
Constipation	7 (8.1)	5 (6.2)	255 (4.5)	297 (5.2)	36 (8.8)	20 (5.5)	18 (5.1)	11 (3.1)
Contusion	5 (5.8)	1 (1.2)	101 (1.8)	95 (1.7)	8 (2.0)	16 (4.4)	13 (3.7)	13 (3.7)
Cough	2 (2.3)	3 (3.7)	215 (3.8)	256 (4.5)	36 (8.8)	24 (6.6)	29 (8.3)	17 (4.8)
Diarrhoea	7 (8.1)	6 (7.4)	344 (6.1)	346 (6.1)	45 (11.0)	29 (8.0)	24 (6.9)	27 (7.6)
Dizziness	4 (4.7)	4 (4.9)	291 (5.2)	276 (4.9)	27 (6.6)	24 (6.6)	19 (5.4)	17 (4.8)
Dyspnoea	3 (3.5)	2 (2.5)	165 (2.9)	179 (3.2)	25 (6.1)	16 (4.4)	8 (2.3)	22 (6.2)

Characteristic, <i>n</i> (%)	Combined SGLT-2i and							
	GLP-1RA use		No SGLT-2i or GLP-1RA		GLP-1RA use only		SGLT-2i use only	
	<i>(n</i> = 167)		use <i>(n</i> = 11 319)		<i>(n</i> = 771)		<i>(n</i> = 706)	
	Finerenone	Placebo	Finerenone	Placebo	Finerenone	Placebo	Finerenone	Placebo
	<i>(n</i> = 86)	<i>(n</i> = 81)	<i>(n</i> = 5643)	<i>(n</i> = 5676)	<i>(n</i> = 410)	<i>(n</i> = 361)	<i>(n</i> = 350)	<i>(n</i> = 356)
Glomerular filtration rate decreased	6 (7.0)	2 (2.5)	298 (5.3)	246 (4.3)	24 (5.9)	18 (5.0)	20 (5.7)	8 (2.2)
Hyperkalaemia	9 (10.5)	4 (4.9)	701 (12.4)	352 (6.2)	43 (10.5)	20 (5.5)	26 (7.4)	6 (1.7)
Hypertension	3 (3.5)	5 (6.2)	374 (6.6)	519 (9.1)	29 (7.1)	32 (8.9)	12 (3.4)	25 (7.0)
Hypoglycaemia	3 (3.5)	2 (2.5)	301 (5.3)	344 (6.1)	22 (5.4)	12 (3.3)	14 (4.0)	17 (4.8)
Hypotension	6 (7.0)	3 (3.7)	230 (4.1)	148 (2.6)	31 (7.6)	15 (4.2)	15 (4.3)	11 (3.1)
Influenza	7 (8.1)	4 (4.9)	206 (3.7)	229 (4.0)	28 (6.8)	21 (5.8)	16 (4.6)	13 (3.7)
Limb injury	0 (0)	1 (1.2)	130 (2.3)	112 (2.0)	24 (5.9)	14 (3.9)	11 (3.1)	10 (2.8)
Muscle spasms	5 (5.8)	2 (2.5)	182 (3.2)	177 (3.1)	24 (5.9)	10 (2.8)	13 (3.7)	18 (5.1)
Nasopharyngitis	5 (5.8)	9 (11.1)	431 (7.6)	459 (8.1)	58 (14.1)	50 (13.9)	53 (15.1)	47 (13.2)

Characteristic, <i>n</i> (%)	Combined SGLT-2i and							
	GLP-1RA use		No SGLT-2i or GLP-1RA		GLP-1RA use only		SGLT-2i use only	
	<i>(n</i> = 167)		use (<i>n</i> = 11 319)		<i>(n</i> = 771)		<i>(n</i> = 706)	
	Finerenone	Placebo	Finerenone	Placebo	Finerenone	Placebo	Finerenone	Placebo
	<i>(n</i> = 86)	<i>(n</i> = 81)	<i>(n</i> = 5643)	<i>(n</i> = 5676)	<i>(n</i> = 410)	<i>(n</i> = 361)	<i>(n</i> = 350)	<i>(n</i> = 356)
Nausea	7 (8.1)	5 (6.2)	145 (2.6)	143 (2.5)	28 (6.8)	15 (4.2)	12 (3.4)	13 (3.7)
Oedema peripheral	9 (10.5)	6 (7.4)	319 (5.7)	517 (9.1)	34 (8.3)	30 (8.3)	22 (6.3)	30 (8.4)
Pain in extremity	7 (8.1)	6 (7.4)	199 (3.5)	219 (3.9)	29 (7.1)	11 (3.0)	17 (4.9)	12 (3.4)
Pneumonia	3 (3.5)	6 (7.4)	229 (4.1)	344 (6.1)	21 (5.1)	21 (5.8)	17 (4.9)	16 (4.5)
Skin ulcer	5 (5.8)	6 (7.4)	114 (2.0)	120 (2.1)	18 (4.4)	17 (4.7)	10 (2.9)	11 (3.1)
Upper respiratory tract infection	11 (12.8)	3 (3.7)	342 (6.1)	349 (6.1)	28 (6.8)	18 (5.0)	26 (7.4)	24 (6.7)
Urinary tract infection	9 (10.5)	2 (2.5)	365 (6.5)	373 (6.6)	34 (8.3)	27 (7.5)	22 (6.3)	30 (8.4)
Vomiting	4 (4.7)	3 (3.7)	106 (1.9)	111 (2.0)	25 (6.1)	17 (4.7)	9 (2.6)	5 (1.4)

Safety analysis set included 6489 and 6474 participants in the finerenone and placebo treatment groups, respectively, who received any combined SGLT-2i and/or GLP-1RA use at baseline. AEs ordered alphabetically by preferred term. A participant was counted only once within each preferred term. All interruptions were excluded from the person-time at risk: i.e., for participants with an interruption, events in the period from interruption start + 3 days until end of interruption were not considered.

AE, adverse event; GLP-1RA, glucagon-like peptide-1 receptor agonist; SAS, safety analysis set; SGLT-2i, sodium-glucose cotransporter-2 inhibitor.



CONSORT 2010 checklist of information to include when reporting a randomised trial*

	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	<u>1</u>
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	<u>3–4</u>
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	<u>5–6</u>
	2b	Specific objectives or hypotheses	<u>6</u>
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	<u>6</u>
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	<u>n/a</u>
Participants	4a	Eligibility criteria for participants	<u>6</u>
	4b	Settings and locations where the data were collected	<u>6</u>
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	<u>7</u>
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	<u>7–8</u>
	6b	Any changes to trial outcomes after the trial commenced, with reasons	<u>n/a</u>
Sample size	7a	How sample size was determined	<u>6</u>
	7b	When applicable, explanation of any interim analyses and stopping guidelines	<u>n/a</u>
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	<u>6</u>
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	<u>6–7</u>
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	<u>6</u>
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	<u>6</u>

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6
	11b	If relevant, description of the similarity of interventions	7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8–9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	6
	13b	For each group, losses and exclusions after randomisation, together with reasons	6
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	31–37
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	8, 31–37
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9–11
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	11, 12, 37–42
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	12–16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12–16
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	online
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	20

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*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.

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