SUPPLEMENTARY DATA

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SUPPLEMENTARY DATA

Supplementary Material

TEXT

Results

Gastric emptying

The post-prandial rate of gastric emptying ($AUC_{0\text{-}60min,\ paracetamol}$, maximum concentration [$C_{max,\ paracetamol}$]) was delayed within the first hour of the standardized breakfast meal for all semaglutide doses compared with placebo (up to 45% delay 1.6 mg E vs placebo; $p<0.01$), but no overall effect (i.e., within the 4-hour duration of the meal, $AUC_{0\text{-}240min,\ paracetamol}$) on gastric emptying was observed. Compared with the liraglutide groups, the effect on overall gastric emptying was not more pronounced with semaglutide ($AUC_{0\text{-}240min,\ paracetamol}$; supplementary Table 1).

Fasting plasma insulin and C-peptide

There was an increase in mean fasting plasma insulin from baseline to Week 12 with all semaglutide doses (mean change ranged from 8.8 to 17.3 pmol/L) with the exception of 0.8 mg (mean change −16.7 pmol/L). A significantly greater increase in fasting plasma insulin was observed for semaglutide 0.2−0.4 mg and 0.8 mg E−1.6 mg E versus placebo ($p<0.05$; supplementary Table 1). No treatment differences were apparent between semaglutide and liraglutide. In addition, a significantly greater increase in fasting C-peptide was observed from baseline to Week 12 with 0.8 mg E semaglutide versus placebo ($p<0.05$; supplementary Table 1). No treatment differences were apparent between semaglutide and liraglutide.

HOMA-B and HOMA-IR

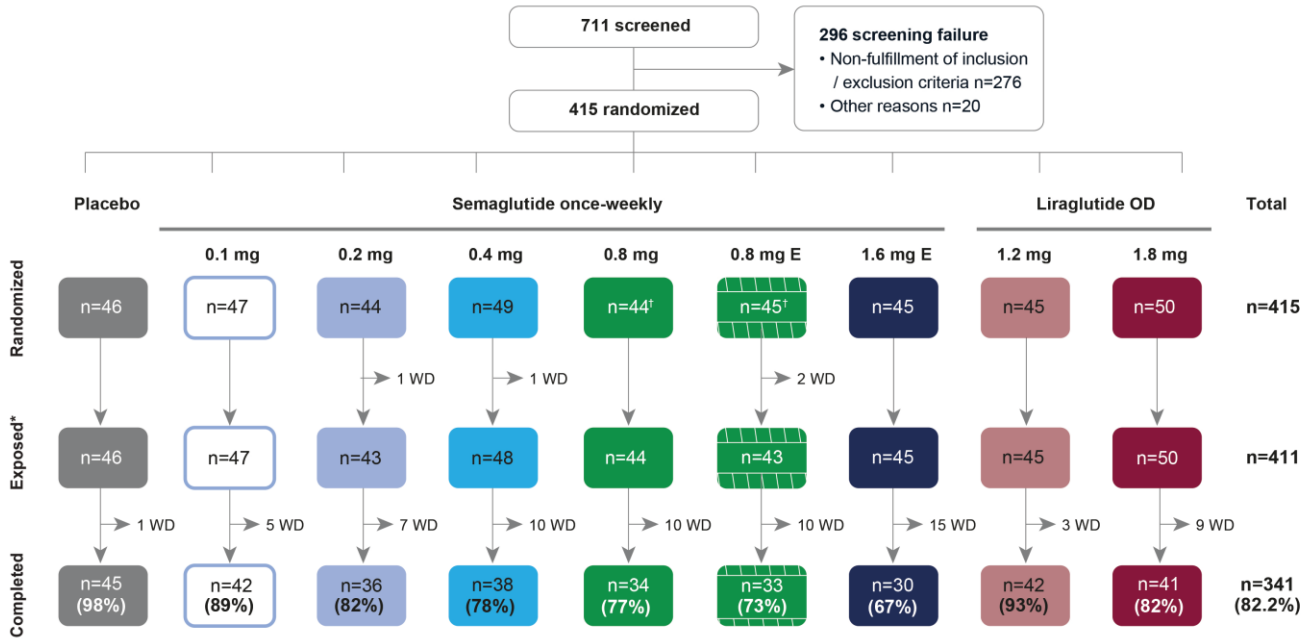
HOMA-B increased dose-dependently from baseline to Week 12 with semaglutide 0.1–1.6 mg E (change from baseline ranged from 8.4 to 57.0%) and was significantly higher with semaglutide 0.4–1.6 mg E versus placebo at Week 12 ($p<0.01$; supplementary Table 1). No treatment differences were apparent between semaglutide and liraglutide. No consistent patterns or trends in HOMA-IR were seen across the treatment groups and no significant difference was observed between any of the semaglutide groups versus placebo. There were no significant differences between treatment groups for the fasting insulin/pro-insulin ratio, except for a higher value in the semaglutide 1.6 mg E group versus placebo (ETD % [95% CI]: 8.5 [4.6;12.4]; $p<0.0001$).

Lipids

Mean baseline fasting lipids for all treatment groups were within or close to recommended levels, according to ADA 2014 targets (1). Approximately 30% of all patients were receiving lipid-lowering medication at baseline. After 12 weeks of treatment, a modest dose-dependent reduction in TC and LDL-C from baseline values was observed with semaglutide 0.2–1.6 mg E (TC: –0.17 mmol/L to –0.60 mmol/L; LDL-C: –0.18 to –0.49 mmol/L). Reductions in TC and LDL-C were statistically significant, compared with placebo, in the semaglutide 0.8 mg and 1.6 mg E groups (TC: $p<0.01$ and $p<0.0001$, respectively; LDL-C: $p<0.05$ for both groups). No clinically meaningful changes in HDL-C, VLDL-C and TG from baseline to end of treatment were seen in any of the treatment groups.

SUPPLEMENTARY DATA

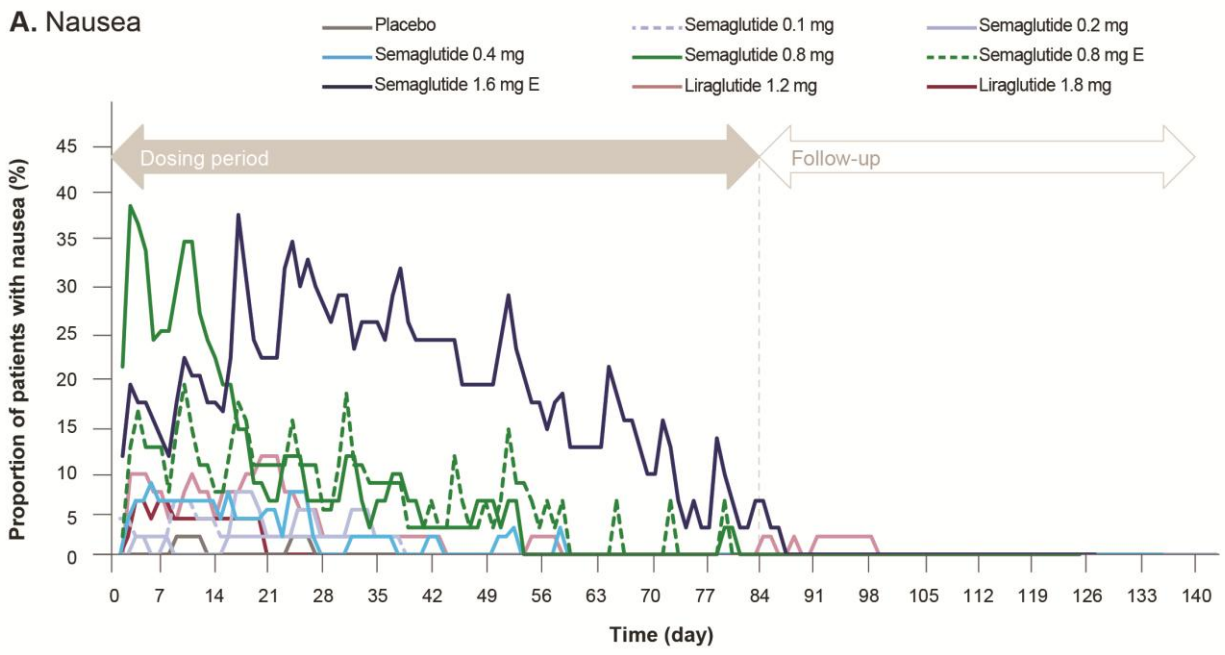
Supplementary Figure 1. Patient disposition.



*Number of subjects exposed to randomized treatment. Data are N (%); OD, once-daily; E = with dose escalation; WD = withdrawals. †Two subjects randomized to semaglutide 0.8 mg were mistakenly dose escalated, actual treatment 0.8 mg E; two subjects randomized to semaglutide 0.8 mg E were mistakenly dose escalated, actual treatment to 1.6 mg E.

SUPPLEMENTARY DATA

Supplementary Figure 2. Proportion of patients with (a) nausea and (b) vomiting by day.

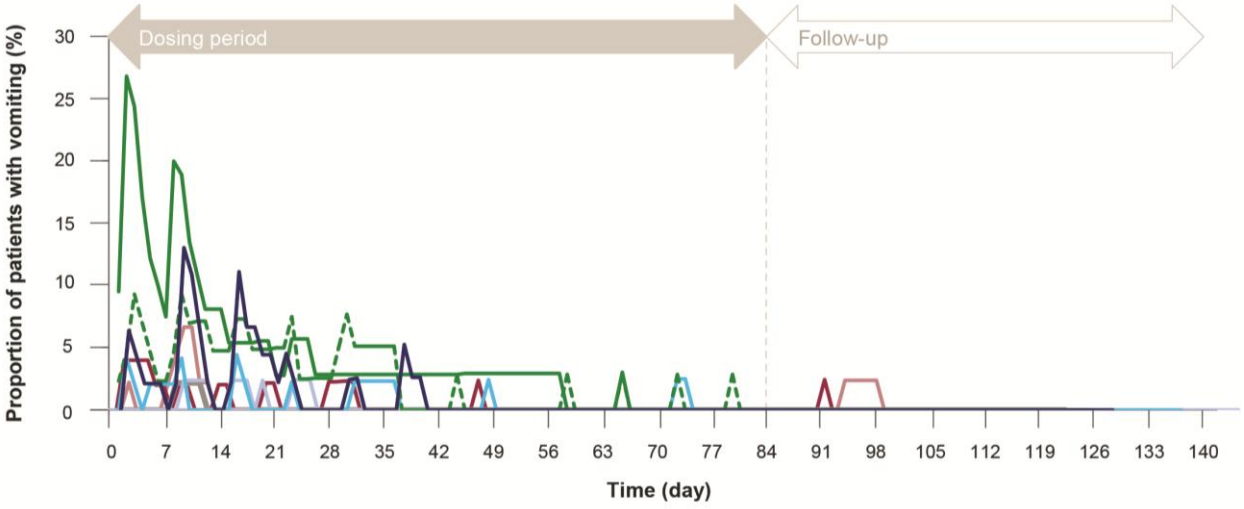


Number of patients at risk

46	46	45	45	placebo
47	44	44	43	semaglutide 0.1 mg
43	41	39	36	semaglutide 0.2 mg
48	43	40	39	semaglutide 0.4 mg
42	35	34	31	semaglutide 0.8 mg
43	39	36	35	semaglutide 0.8 mg E
47	42	35	32	semaglutide 1.6 mg E
45	44	42	42	liraglutide 1.2 mg
50	44	42	41	liraglutide 1.8 mg

SUPPLEMENTARY DATA

B. Vomiting



Number of patients at risk

46	46	45	45	placebo
47	45	44	43	semaglutide 0.1 mg
43	41	39	36	semaglutide 0.2 mg
48	43	40	39	semaglutide 0.4 mg
42	35	34	32	semaglutide 0.8 mg
43	39	36	35	semaglutide 0.8 mg E
47	43	35	32	semaglutide 1.6 mg E
45	44	42	42	liraglutide 1.2 mg
50	44	42	41	liraglutide 1.8 mg

SUPPLEMENTARY DATA

Supplementary Table 1. Mean change in fasting glucagon, fasting insulin, fasting C-peptide, HOMA-B, HOMA-IR, food consumption during meal test, assessment of postprandial hunger, fullness, satiety, prospective meal consumption, thirst, wellbeing and nausea from baseline to Week 12; and mean and incremental glucose AUC during the meal and gastric emptying (measured using paracetamol concentrations) at Week 12.

	Placebo	**Semaglutide**						**Liraglutide**	
		0.1 mg	0.2 mg	0.4 mg	0.8 mg	0.8 mg E	1.6 mg E	1.2 mg	1.8 mg
Fasting glucagon, ng/L									
Mean change from baseline (SD)	5.5 (31.3)	4.9 (30.6)	0.4 (27.3)	–5.3 (38.9)	–13.4 (32.2)	–15.0 (47.5)	–12.4 (41.0)	–8.1 (50.4)	–3.7 (34.9)
ETD vs placebo (95%CI)		–3.3 (–18.8;12.2)	–3.6 (–19.9;12.6)	–8.0 (–23.9;7.8)	–13.4 (–29.6;2.8)	–14.1 (–30.1;1.8)	–16.4* (–32.7;−0.1)	–12.8 (–25.1;−0.4)	–10.9 (–22.8;1.1)
ETD vs liraglutide 1.2 mg (95%CI)		9.5 (–2.7;21.7)	9.1 (–3.6;21.8)	4.7 (–7.9;17.3)	−0.7 (–13.4;12.1)	−1.4 (–14.0;11.2)	−3.6 (–16.3;9.0)		
ETD vs liraglutide 1.8 mg (95%CI)		7.6 (–4.1;19.3)	7.2 (–5.1;19.5)	2.9 (–9.1;14.8)	−2.6 (–14.9;9.8)	−3.3 (–15.4;8.9)	−5.5 (–17.7;6.7)		
Fasting insulin, pmol/L									
Mean change from baseline (SD)	–18.1 (53.4)	8.8 (47.5)	17.3 (57.5)	13.6 (53.1)	–16.7 (48.1)	10.6 (55.9)	14.2 (47.3)	13.1 (42.4)	11.6 (37.8)
ETD vs placebo (95%CI)		19.3 (–6.5;45.1)	32.4* (5.7;59.0)	31.8** (5.9;57.7)	10.5 (–16.5;37.5)	33.1* (5.8;60.4)	32.7* (4.8;60.6)	23.7 (3.9;43.6)	20.6 (0.4;40.8)
ETD vs liraglutide 1.2 mg (95%CI)		–4.4 (–24.2;15.4)	8.7 (–12.0;29.3)	8.1 (–12.2;28.3)	–13.3 (–34.1;7.6)	9.4 (–11.8;30.6)	9.0 (–12.4;30.4)		
ETD vs liraglutide 1.8 mg (95%CI)		–1.3 (–21.1;18.5)	11.7 (–9.0;32.5)	11.2 (–9.0;31.3)	–10.2 (–31.6;11.3)	12.5 (–9.1;34.0)	12.1 (–9.5;33.6)		
Fasting C-peptide, nmol/L									
Mean change from baseline (SD)	–0.1 (0.3)	–0.0 (0.4)	0.1 (0.4)	0.1 (0.4)	–0.0 (0.4)	0.2 (0.4)	0.0 (0.3)	0.1 (0.3)	0.1 (0.3)
ETD vs		0.0	0.1	0.1	0.1	0.2*	0.1	0.1	0.1

SUPPLEMENTARY DATA

	Placebo	Semaglutide						Liraglutide	
		0.1 mg	0.2 mg	0.4 mg	0.8 mg	0.8 mg E	1.6 mg E	1.2 mg	1.8 mg
placebo (95%CI)		(–0.2;0.2)	(–0.1;0.3)	(–0.1;0.3)	(–0.1;0.3)	(0.0;0.4)	(–0.1;0.3)	(–0.0;0.3)	(–0.0;0.3)
ETD vs liraglutide 1.2 mg (95%CI)		–0.1 (–0.3;0.0)	0.0 (–0.1;0.2)	0.0 (–0.1;0.2)	–0.1 (–0.2;0.1)	0.1 (–0.1;0.3)	–0.0 (–0.2;0.1)		
ETD vs liraglutide 1.8 mg (95%CI)		–0.1 (–0.2;0.1)	0.0 (–0.1;0.2)	0.0 (–0.1;0.2)	–0.0 (–0.2;0.1)	0.1 (–0.0;0.3)	–0.0 (–0.2;0.2)		
HOMA-B, %									
Mean change from baseline (SD)	–7.3 (35.6)	8.4 (30.2)	21.7 (37.9)	29.4 (35.8)	48.6 (113.9)	46.7 (52.0)	57.0 (68.9)	24.6 (35.3)	31.8 (31.9)
ETD vs placebo (95%CI)		13.7 (−19.5;46.8)	27.7 (–6.0;61.3)	42.5** (9.4;75.6)	53.0*** (18.9;87.2)	54.4*** (18.1;90.7)	64.3**** (28.5;100.1)	32.7 (7.3;58.1)	42.7 (15.8;69.5)
ETD vs liraglutide 1.2 mg (95%CI)		–19.0 (–44.5;6.5)	–5.0 (–31.3;21.2)	9.8 (–16.1;35.8)	20.3 (–6.3;47.0)	21.7 (–6.5;49.8)	31.6 (4.0;59.1)		
ETD vs liraglutide 1.8 mg (95%CI)		–29.0 (–55.6;–2.3)	–15.0 (–42.4;12.5)	–0.2 (–26.8;26.5)	10.4 (–17.9;38.6)	11.7 (–17.6;41.1)	21.6 (–6.8;50.1)		
HOMA-IR, %									
Mean change from baseline (SD)	–1.0 (3.8)	0.5 (3.0)	0.3 (4.1)	–0.1 (3.5)	–2.6 (3.6)	–0.5 (3.4)	–1.4 (2.6)	0.1 (2.7)	–0.4 (2.1)
ETD vs placebo (95%CI)		0.7 (–0.8;2.2)	1.1 (–0.4;2.7)	0.5 (–1.0;2.0)	–0.6 (–2.1;1.0)	0.5 (–1.1;2.2)	0.0 (–1.6;1.7)	0.3 (–0.8;1.5)	–0.4 (–1.6;0.8)
ETD vs liraglutide 1.2 mg (95%CI)		0.4 (–0.8;1.5)	0.8 (–0.4;2.0)	0.2 (–1.0;1.4)	–0.9 (–2.1;0.3)	0.2 (–1.1;1.5)	–0.3 (–1.6;1.0)		
ETD vs liraglutide 1.8 mg (95%CI)		1.1 (–0.1;2.3)	1.6 (0.3;2.8)	1.0 (–0.3;2.2)	–0.2 (–1.4;1.1)	0.9 (–0.4;2.3)	0.4 (–0.9;1.7)		
Food consumption during meal test†, g									
Mean	–12.2	–4.9	–15.4	–7.4	–36.4	–16.7	–39.8	–8.2	–6.0

SUPPLEMENTARY DATA

	Placebo	Semaglutide						Liraglutide	
		0.1 mg	0.2 mg	0.4 mg	0.8 mg	0.8 mg E	1.6 mg E	1.2 mg	1.8 mg
change from baseline (SD)	(45.4)	(22.6)	(41.3)	(34.2)	(70.0)	(68.0)	(79.7)	(30.2)	(37.1)
Food consumption during meal test†, kJ									
Mean change from baseline (SD)	–62.5 (232.1)	–25.0 (115.6)	–78.1 (209.0)	–21.1 (87.0)	–171.3 (328.9)	–73.7 (300.0)	–203.5 (407.5)	–41.9 (154.5)	–22.4 (138.1)
PPG $AUC_{0-240\ min}$, mmol/L*h									
Estimated LS mean at Week 12	47.9	44.7	41.7	37.4	35.1	34.1	31.0	39.9	34.8
ETR vs placebo (95%CI)		0.9 (0.8;1.1)	0.9* (0.8;1.0)	0.8**** (0.7;0.9)	0.7**** (0.7;0.8)	0.7**** (0.6;0.8)	0.7**** (0.6;0.7)	0.8 (0.8;0.9)	0.7 (0.7;0.8)
ETR vs liraglutide 1.2 mg (95%CI)		1.1 (1.0;1.2)	1.0 (1.0;1.2)	0.9 (0.9;1.0)	0.9 (0.8;1.0)	0.9 (0.8;0.9)	0.8 (0.7;0.9)		
ETR vs liraglutide 1.8 mg (95%CI)		1.3 (1.2;1.4)	1.2 (1.1;1.3)	1.1 (1.0;1.2)	1.0 (0.9;1.1)	1.0 (0.9;1.1)	0.9 (0.8;1.0)		
PPG incremental $AUC_{0-240\ min}$, mmol/L*h									
Estimated LS mean at Week 12	14.9	12.2	11.8	10.2	9.3	9.0	6.5	11.1	8.9
ETD vs placebo (95%CI)		–2.7 (–5.7;0.4)	–3.1 (–6.4;0.2)	–4.7* (–7.9; –1.5)	–5.6*** (–8.8; –2.3)	–5.9**** (–9.3; –2.6)	–8.4**** (–12.0; –4.8)	–3.8 (–6.1; –1.4)	–6.0 (–8.5; –3.6)
ETD vs liraglutide 1.2 mg (95%CI)		1.1 (–1.3;3.5)	0.7 (–1.9;3.2)	–0.9 (–3.4; 1.6)	–1.8 (–4.3; 0.8)	–2.2 (–4.8; 0.4)	–4.6 (–7.4; –1.9)		
ETD vs liraglutide 1.8 mg (95%CI)		3.4 (1.0;5.8)	2.9 (0.3;5.5)	1.3 (–1.2; 3.9)	0.5 (–2.1; 3.0)	0.1 (–2.6; 2.7)	–2.4 (–5.2; 0.4)		
$AUC_{0-60\ min,\ paracetamol}$, ng/mL*h‡									
Estimated LS mean at Week 12	6868	6626	5585	5356	5308	6051	3773	4905	4894
ETR vs placebo		1.0 (0.7;1.3)	0.8 (0.6;1.1)	0.8 (0.6;1.1)	0.8 (0.6;1.1)	0.9 (0.7;1.2)	0.6** (0.4;0.8)		

SUPPLEMENTARY DATA

	Placebo	Semaglutide						Liraglutide	
		0.1 mg	0.2 mg	0.4 mg	0.8 mg	0.8 mg E	1.6 mg E	1.2 mg	1.8 mg
(90%CI)									
ETR vs liraglutide 1.2 mg (95%CI)	0.7 (0.5;1.0)	1.4 (0.9;2.0)	1.1 (0.8;1.7)	1.1 (0.7;1.6)	1.1 (0.7;1.6)	1.2 (0.8;1.8)	0.8 (0.5;1.2)		
ETR vs liraglutide 1.8 mg (95%CI)	0.7 (0.5;1.0)	1.4 (0.9;1.9)	1.1 (0.8;1.7)	1.1 (0.8;1.6)	1.1 (0.7;1.6)	1.2 (0.8;1.8)	0.8 (0.5;1.2)		
$AUC_{0–240\ min,\ paracetamol}$, ng/mL*h‡									
Estimated LS mean at Week 12	36247	36878	34657	32063	31530	34197	32742	31438	32812
ETR vs placebo (90%CI)		1.0 (0.9;1.2)	1.0 (0.8;1.1)	0.9 (0.8;1.0)	0.9 (0.8;1.0)	0.9 (0.8;1.1)	0.9 (0.8;1.0)		
ETR vs liraglutide 1.2 mg (95%CI)	0.9 (0.7;1.0)	1.2* (1.0;1.4)	1.1 (0.9;1.3)	1.0 (0.9;1.2)	1.0 (0.9;1.2)	1.1 (0.9;1.3)	1.0 (0.9;1.2)		
ETR vs liraglutide 1.8 mg (95%CI)	0.9 (0.8;1.1)	1.1 (1.0;1.3)	1.1 (0.9;1.2)	1.0 (0.8;1.2)	1.0 (0.8;1.1)	1.0 (0.9;1.2)	1.0 (0.8;1.2)		
Average postprandial hunger, fullness, satiety, prospective meal consumption, thirst, wellbeing and nausea‡									
Hunger, ETD vs placebo (95%CI)		–0.1 (–8.4;8.3)	–1.1 (–9.8;7.5)	2.1 (–6.4;10.6)	–7.2 (–15.8;1.5)	0.1 (–8.7;9.0)	–6.8 (–16.2;2.5)	0.3 (–6.0;6.6)	–2.9 (–9.4;3.6)
Fullness, ETD vs placebo (95%CI)		2.0 (–8.3;12.2)	7.6 (–3.1;18.2)	2.1 (–8.3;12.5)	14.0** (3.3;24.6)	3.7 (–7.1;14.4)	10.0 (–1.5;21.5)	–0.1 (–7.8;7.6)	4.3 (–3.7;12.2)
Satiety, ETD vs placebo (95%CI)		0.7 (–9.5;10.9)	4.9 (–5.6;15.5)	0.2 (–10.2;10.6)	9.7 (–0.9;20.3)	3.1 (–7.7;13.8)	11.1 (–0.4;22.6)	–3.5 (–11.3;4.3)	2.0 (–6.1;10.0)
Prospective meal consumption, ETD vs placebo (95%CI)		–1.3 (–10.1;7.5)	–4.8 (–13.9;4.4)	–0.5 (–9.5;8.5)	–10.8* (–20.0;–1.6)	0.3 (–9.0;9.6)	–11.7* (–21.7;–1.8)	1.6 (–5.1;8.3)	–2.0 (–8.9;5.0)

SUPPLEMENTARY DATA

	Placebo	Semaglutide						Liraglutide	
		0.1 mg	0.2 mg	0.4 mg	0.8 mg	0.8 mg E	1.6 mg E	1.2 mg	1.8 mg
Thirst, ETD vs placebo (95%CI)		4.2 (–6.6;15.0)	–5.5 (–16.7;5.7)	1.6 (–9.4;12.6)	0.1 (–11.2;11.4)	–0.2 (–11.7;11.2)	–4.2 (–16.4;8.0)	–2.6 (–10.9;5.6)	–5.4 (–13.8;3.0)
Wellbeing, ETD vs placebo (95%CI)		3.0 (–5.3;11.3)	1.4 (–7.2;10.0)	1.1 (–7.3;9.6)	–0.8 (–9.5;7.9)	4.4 (–4.4;13.2)	0.3 (–9.1;9.6)	–2.5 (–8.9;3.9)	1.2 (–5.4;7.7)
Nausea, ETD vs placebo (95%CI)		0.3 (–6.0;6.5)	–0.1 (–6.6;6.4)	0.4 (–5.9;6.8)	4.4 (–2.1;11.0)	–0.5 (–7.1;6.1)	5.3 (–1.8;12.3)	2.9 (–1.9;7.6)	1.3 (–3.7;6.2)

ETD, estimated treatment difference; ETR, estimated treatment ratio; LS mean, least squares mean; SD, standard deviation. *p<0.05; **p<0.01; ***p<0.001; ****p<0.0001.
All values are means; full analysis set, last observation carried forward.
Estimates are from an ANOVA model with treatment, country and previous treatment as fixed effects and baseline value as covariate; CIs for treatment differences versus placebo are based on Dunnett's method (with 6 comparisons); CIs for treatment differences versus liraglutide are not corrected for multiple testing.
†After overnight fasting, subjects were asked (but not forced) to consume within 15 minutes a standard breakfast meal of fixed energy and macronutrient content (energy: 2 MJ; 79.2 energy percent [E%] from carbohydrates, 8.8 E% from fat and 12 E% from protein).
‡Paracetamol tablets (1.5 g) were given with water at the start of the meal in order to measure gastric emptying. Samples for measurement of paracetamol concentration ($AUC_{0–60min, paracetamol}$, $AUC_{0–240min, paracetamol}$) were collected 10 minutes before, and 15, 30, 45, 60, 90, 120, 180 and 240 minutes after, the meal test. In addition, the effects of semaglutide and liraglutide on gastric emptying were evaluated by assessment of sensations of appetite, nausea, thirst and wellbeing, using a visual analog scale (2).

SUPPLEMENTARY DATA

Supplementary Table 2. TEAEs, by severity

TEAEs, n (%)	**Placebo**	**Semaglutide**						**Liraglutide**	
		0.1 mg	0.2 mg	0.4 mg	0.8 mg	0.8 mg E	1.6 mg E	1.2 mg	1.8 mg
Total	48 (100)	76 (100)	55 (100)	134 (100)	141 (100)	142 (100)	219 (100)	83 (100)	90 (100)
Mild	31 (64.6)	54 (71.1)	40 (72.7)	96 (71.6)	85 (60.3)	87 (61.3)	122 (55.7)	52 (62.7)	51 (56.7)
Moderate	17 (35.4)	21 (27.6)	13 (23.6)	32 (23.9)	50 (35.5)	49 (34.5)	82 (37.4)	29 (34.9)	37 (41.1)
Severe	0 (0)	1 (1.3)	2 (3.6)	6 (4.5)	6 (4.3)	6 (4.2)	15 (6.8)	2 (2.4)	2 (2.2)

TEAE, treatment-emergent adverse event

Supplementary Table 3. GI AEs, by severity

GI AEs, n (%)	**Placebo**	**Semaglutide**						**Liraglutide**	
		0.1 mg	0.2 mg	0.4 mg	0.8 mg	0.8 mg E	1.6 mg E	1.2 mg	1.8 mg
Total	8 (100)	22 (100)	18 (100)	60 (100)	92 (100)	98 (100)	121 (100)	36 (100)	36 (100)
Mild	7 (87.5)	18 (81.8)	14 (77.8)	44 (73.3)	53 (57.6)	61 (62.2)	65 (53.7)	20 (55.6)	18 (50.0)
Moderate	1 (12.5)	4 (18.2)	4 (22.2)	14 (23.3)	34 (37.0)	34 (34.7)	47 (38.8)	14 (38.9)	17 (47.2)
Severe	0 (0)	0 (0)	0 (0)	2 (3.3)	5 (5.4)	3 (3.1)	9 (7.4)	2 (5.6)	1 (2.8)

GI, gastrointestinal

References

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