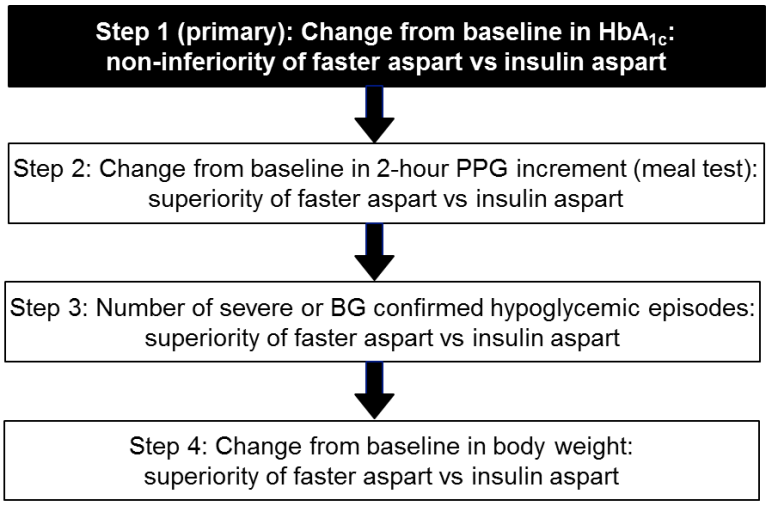
SUPPLEMENTARY DATA

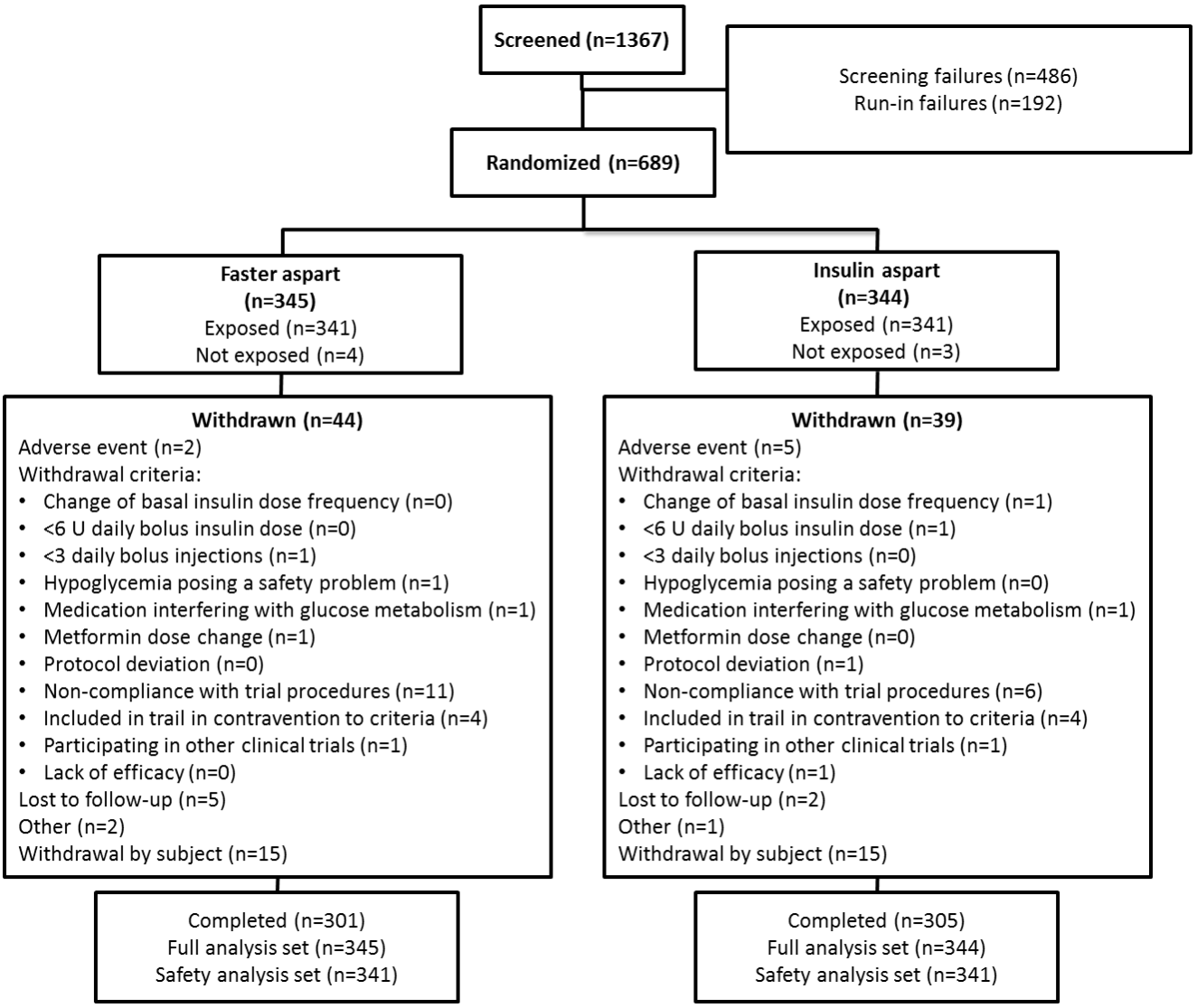
Supplementary Figure 1. Step-wise hierarchical testing procedure for confirmatory endpoints



Superiority of faster aspart in terms of change in 2-h PPG increment (meal test) from baseline could not be confirmed (Step 2), and the hierarchical testing procedure was stopped. BG, blood glucose; faster aspart; fast-acting insulin aspart; PPG, postprandial plasma glucose.

SUPPLEMENTARY DATA

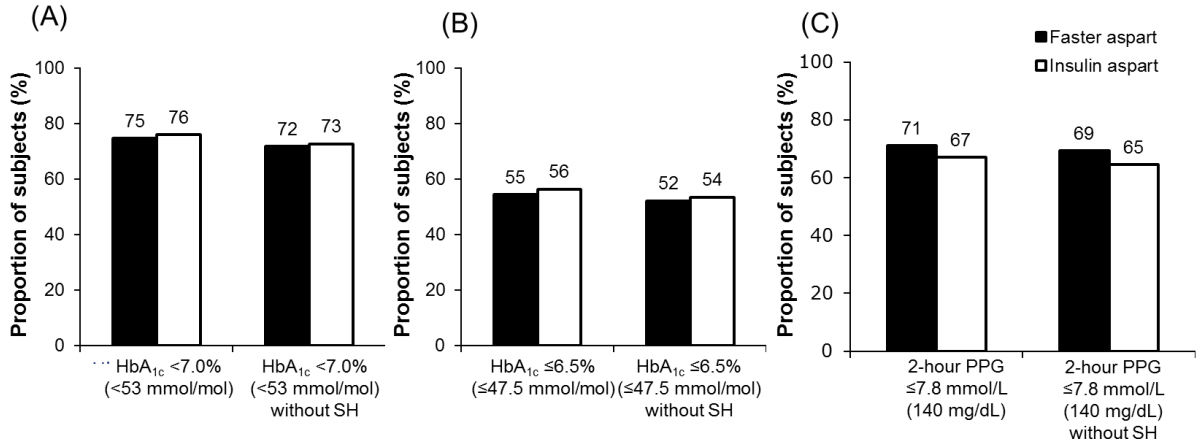
Supplementary Figure 2. Subject disposition



A total of 881 subjects entered the run-in period of the trial; the most common reason for failure during the run-in period was inability to meet the criteria for HbA_{1c} (7.0–9.5% [53–80 mmol/mol]) prior to the randomization visit. Faster aspart, fast-acting insulin aspart; HbA_{1c}, glycosylated hemoglobin.

SUPPLEMENTARY DATA

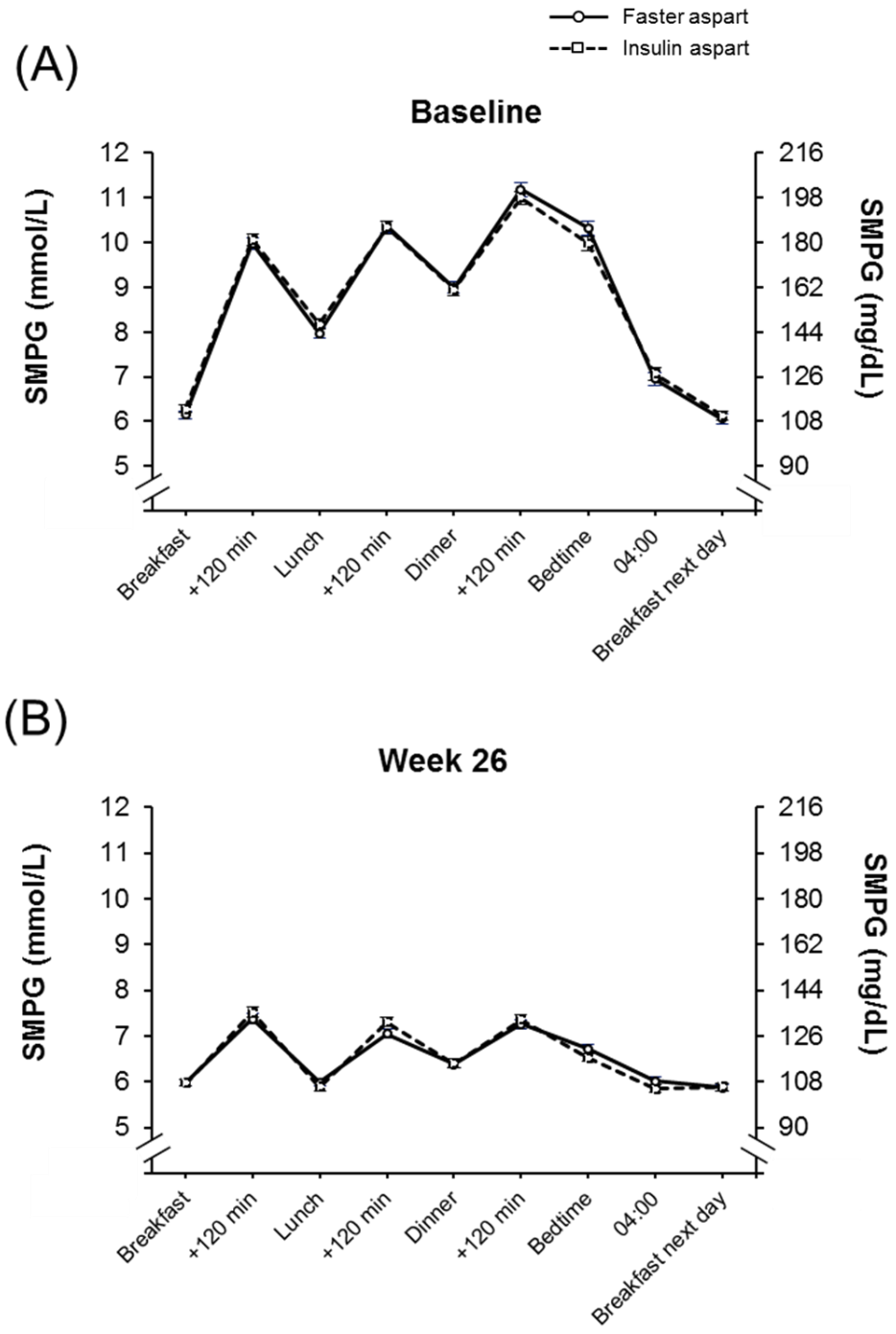
Supplementary Figure 3. Proportion of subjects achieving glycemic targets



(A) HbA_{1c} responders with HbA_{1c} <7.0% (53 mmol/mol) and HbA_{1c} <7.0% (53 mmol/mol) without SH; (B) HbA_{1c} responders with HbA_{1c} ≤6.5% (47.5 mmol/mol) and HbA_{1c} ≤6.5% (47.5 mmol/mol) without SH; (C) PPG responders with 2-h PPG ≤7.8 mmol/L (140 mg/dL) and PPG responders with 2-h PPG ≤7.8 mmol/L (140 mg/dL) without SH (based on SMPG). Faster aspart; fast-acting insulin aspart; HbA_{1c}, glycosylated hemoglobin; PPG, postprandial plasma glucose; SH, severe hypoglycemia; SMPG, self-monitored plasma glucose.

SUPPLEMENTARY DATA

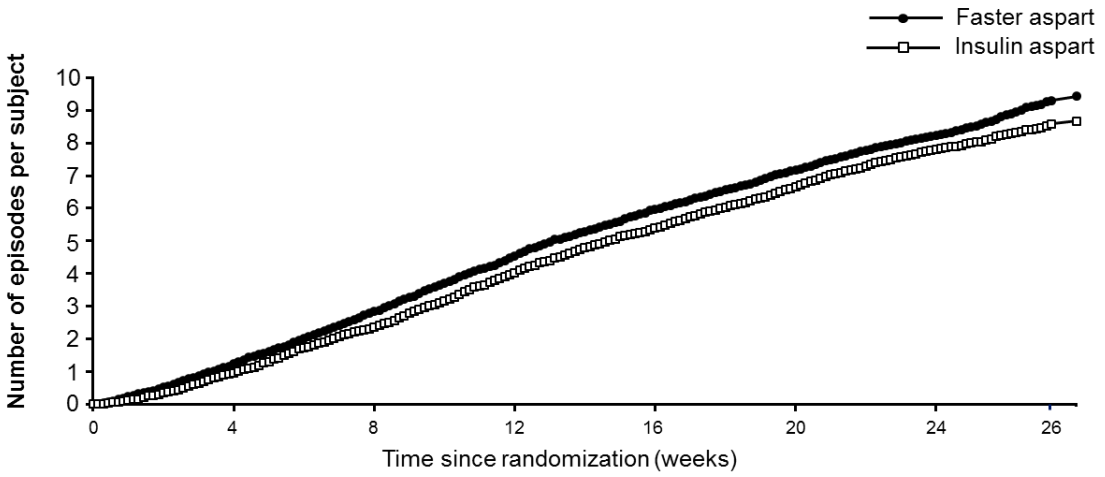
Supplementary Figure 4. SMPG profiles at baseline (A) and Week 26 (B)



The conversion factor between mmol/L and mg/dL is 18. Faster aspart, fast-acting insulin aspart; SMPG, self-monitored plasma glucose.

SUPPLEMENTARY DATA

Supplementary Figure 5. Treatment-emergent hypoglycemia (severe or BG confirmed) mean cumulative function



Severe or BG confirmed hypoglycemia was defined as an episode that is severe according to the ADA classification (21) or BG confirmed by a PG value <3.1 mmol/L (56 mg/dL) with or without hypoglycemic symptoms. ADA, American Diabetes Association; BG, blood glucose; faster aspart, fast-acting insulin aspart; PG, plasma glucose.

SUPPLEMENTARY DATA

Supplementary Table 1. Basal and bolus insulin dose adjustments

Basal insulin dose adjustments **Increase in insulin glargine dose** **Mean of three breakfast SMPG values** **mmol/L**	**mg/dL**	**Dose adjustment (U)**
4.0–5.0	71–90	No adjustment
5.1–7.0	91–126	+2
7.1–8.0	127–144	+4
8.1–9.0	145–162	+6
>9.0	>162	+8
Reduction in insulin glargine dose **Lowest pre-breakfast SMPG value** **mmol/L**	**mg/dL**	**Dose adjustment (U)**
<3.1	<56	–4 (or 10% if dose >45 U)
3.1–3.9	56–70	–2 (or 5% if dose >45 U)
Bolus insulin dose adjustments **Pre-prandial or bedtime glucose value** **mmol/mol**	**mg/dL**	**Dose adjustment (U)**
<4.0	<71	–1
4.0–6.0	71–108	No adjustment
>6.0	>108	+1

Basal insulin dose adjustments were performed once-weekly during the run-in period. After randomization, bolus insulin (faster aspart or insulin aspart) dose adjustments were performed daily by the subject and reviewed weekly by the investigator. The conversion factor between mmol/L and mg/dL is 18. Faster aspart, fast-acting insulin aspart; SMPG, self-monitored plasma glucose.

SUPPLEMENTARY DATA

Supplementary Table 2. All reported endpoints*, including step-wise hierarchical testing procedure for confirmatory endpoints.

Primary endpoint	• Change from baseline in HbA_{1c} after 26 weeks of randomized treatment (Step 1†)
Confirmatory secondary endpoints	• Change from baseline in 2-hour PPG increment (meal test) after 26 weeks of randomized treatment (Step 2‡) • Number of treatment-emergent severe or BG confirmed hypoglycemic events from baseline until Week 26 (Step 3‡) • Change from baseline in body weight after 26 weeks of randomized treatment (Step 4‡)
Supportive secondary efficacy endpoints	• HbA_{1c} responder endpoints after 26 weeks of randomized treatment: – Percentage of subjects reaching HbA_{1c} <7% (53.0 mmol/mol) or HbA_{1c} ≤6.5% (47.5 mmol/mol) – Percentage of subjects reaching HbA_{1c} <7% (53.0 mmol/mol) or HbA_{1c} ≤6.5% (47.5 mmol/mol) without severe hypoglycemia • Change from baseline in PPG from meal test (at 1, 2, 3 and 4 hours separately*) after 26 weeks of randomized treatment • Change from baseline in PPG increment from meal test (at 1, 3 and 4 hour separately*) after 26 weeks of randomized treatment • 7-9-7-point SMPG profiles after 26 weeks of randomized treatment: – Change from baseline in mean SMPG profile – Change from baseline in mean PPG increment (7-9-7-point profile) • PPG responders (overall mean 2-h PPG) after 26 weeks of randomized treatment (7-9-7-point SMPG profile): – Percentage of subjects reaching overall mean 2-hour PPG (SMPG) ≤7.8 mmol/L (140 mg/dL) – Percentage of subjects reaching overall mean 2-hour PPG (SMPG) ≤7.8 mmol/L (140 mg/dL) without severe hypoglycemia • Change from baseline in 1,5-anhydroglucitol after 26 weeks of randomized treatment • Change from baseline in FPG after 26 weeks of randomized treatment • Change from baseline in daily insulin dose (basal, bolus and total) after 26 weeks of randomized treatment
Supportive secondary safety endpoints	• Number of treatment-emergent adverse events during the trial • Number of hypoglycemic episodes during the trial classified according to the ADA definition and an

	additional Novo Nordisk classification – Number of hypoglycemic episodes from start of meal until 1, 2, 4 and 6 hours after start – Number of daytime (06:00–23:59 h) and nocturnal (00:00–05:59 h) episodes • Number of injection-site reactions • Number of allergic reactions • Change in laboratory safety parameters from baseline • Change in additional safety parameters from baseline

*All endpoints reported in this manuscript were pre-specified. Time points were pre-specified in the statistical analysis plan prior to database lock.
†Step 1: non-inferiority of faster aspart vs insulin aspart; ‡Step 2, 3 and 4: superiority of faster aspart vs insulin aspart.
Superiority of faster aspart in terms of change in 2-h PPG increment (meal test) from baseline could not be confirmed (Step 2), and the hierarchical testing procedure was stopped.
BG, blood glucose; faster aspart, fast-acting insulin aspart; FPG, fasting plasma glucose; PPG, postprandial plasma glucose; SMPG, self-monitored plasma glucose.

SUPPLEMENTARY DATA

Supplementary Table 3. Confirmatory statistical analysis

Endpoint [comparison]		Estimate [95% CI]	*P* value[a]	Conclusion
CONFIRMATORY PRIMARY				
Step 1	**Change from baseline in HbA_{1c} after 26 weeks of treatment** [faster aspart–insulin aspart]	–0.02 [–0.15; –0.10]	<0.0001[a]	*Non-inferiority confirmed*
CONFIRMATORY SECONDARY				
Step 2	**Change from baseline in 2-hour PPG increment after 26 weeks of treatment (meal test)** [faster aspart–insulin aspart]	–0.36 [–0.81; –0.08]	0.1063	*Superiority not confirmed*
Step 3	**Number of treatment emergent severe or BG confirmed hypoglycemic episodes** [faster aspart–insulin aspart]	1.09 [0.88; 1.36]	0.4247	*Testing procedure stopped*
Step 4	**Change from baseline in body weight after 26 weeks of treatment** [faster aspart–insulin aspart]	0.00 [–0.60; 0.61]	0.9879	

[a]*P*-values for non-inferiority are from the 1-sided test; all other *P*-values for superiority are from the 2-sided test. Full analysis set. BG, blood glucose; faster aspart, fast-acting insulin aspart; PPG, postprandial plasma glucose.

SUPPLEMENTARY DATA

Supplementary Table 4. Summary of supportive endpoints

	Faster aspart	Insulin aspart	Estimated OR [95% CI]
HbA_{1c} responders after 26 weeks' treatment, %			
HbA_{1c}<7.0% (53 mmol/mol)	74.8	75.9	1.01 [0.70; 1.44]
HbA_{1c}<7.0% (53 mmol/mol) without SH	71.9	72.7	1.02 [0.73; 1.44]
HbA_{1c} ≤6.5% (47.5 mmol/mol)	54.5	56.4	0.99 [0.73; 1.35]
HbA_{1c} ≤6.5% (47.5 mmol/mol) without SH	52.2	53.5	1.02 [0.75; 1.38]
PPG responders (from 7-9-7-point SMPG profile) after 26 weeks'treatment, %			
PPG ≤7.8mmol/L (140mg/dL)	71.2	67.2	1.18 [0.85; 1.65]
PPG ≤7.8mmol/L (140mg/dL) without SH	69.4	64.5	1.23 [0.89; 1.71]
			ETD [95% CI]
Change from baseline after 26 weeks' treatment			
1-h PPG (meal test)			
mmol/L	–2.11	–1.85	–0.26 [–0.81; 0.28]
mg/dL	–38.03	–33.28	–4.75 [–14.56; 5.06]
2-h PPG (meal test)			
mmol/L	–3.21	–3.18	–0.04 [–0.53; 0.46]
mg/dL	–57.89	–57.25	–0.64 [–9.54; 8.26]
3-h PPG (meal test)			
mmol/L	–3.45	–3.47	0.02 [–0.46; 0.51]
mg/dL	–62.17	–62.61	0.44 [–8.30; 9.19]
4-h PPG (meal test)			
mmol/L	–3.10	–3.15	0.06 [–0.41; 0.52]
mg/dL	–55.78	–56.80	1.03 [–7.37; 9.42]
1-h PPG increment (meal test)			
mmol/L	–2.14	–1.55	–0.59 [–1.09; –0.09]*
mg/dL	–38.54	–27.92	−10.63 [−19.56; −1.69]*
3-h PPG increment (meal test)			
mmol/L	–3.50	–3.18	–0.33 [–0.77; 0.11]
mg/dL	–63.12	–57.22	–5.91 [–13.82; 2.01]
4-h PPG increment (meal test)			
mmol/L	–3.15	–2.87	–0.28 [–0.70; 0.13]
mg/dL	–56.84	–51.76	–5.08 [–12.56; 2.41]
Mean of 7-9-7-point SMPG			
mmol/L	–2.38	–2.33	–0.05 [–0.21; 0.11]
mg/dL	–42.83	–41.99	–0.84 [–3.71; 2.03]
PPG increment, breakfast (from 7-9-7-point SMPG			

profile)			
mmol/L	–2.46	–2.35	–0.11 [–0.40; 0.18]
mg/dL	–44.53	–42.23	–2.31 [–7.44; 2.86]
PPG increment, lunch (from 7-9-7-point SMPG profile)			
mmol/L	–1.19	–0.83	–0.35 [–0.65; –0.05]†
mg/dL	–21.36	–15.00	–6.36 [–11.81; –0.92]†
PPG increment, dinner (from 7-9-7-point SMPG profile)			
mmol/L	–1.27	–1.17	–0.10 [–0.40; 0.20]
mg/dL	–22.89	–21.02	–1.87 [–7.28; 3.55]
PPG increment, all meals (from 7-9-7-point SMPG profile)			
mmol/L	–1.65	–1.44	–0.20 [–0.42; 0.01]
mg/dL	–29.70	–26.03	–3.67 [–7.58; 0.23]
1,5-AG			
µg/mL	5.82	6.25	–0.43 [–1.28; 0.42]
FPG			
mmol/L	0.02	–0.24	0.26 [–0.03; 0.55]
mg/dL	0.36	–4.31	4.67 [–0.49; 9.83]

*P=0.0198; †P=0.0219. PPG increment for the three main meals and 'all meals' is the difference between SMPG values 2 h after a meal and before a meal, and is based on the 7-9-7-point profile. 'All meals' represents the mean of all increments. The conversion factor between mmol/L and mg/dL is 18. 1,5-AG, 1,5-anhydroglucitol; ETD, estimated treatment difference (faster aspart – insulin aspart); faster aspart, fast-acting insulin aspart; FPG, fasting plasma glucose; OR, odds ratio (faster aspart/insulin aspart); PPG, postprandial plasma glucose; SH, severe hypoglycemia; SMPG, self-monitored plasma glucose.

SUPPLEMENTARY DATA

Supplementary Table 5. Daily insulin dosing (U and U/kg) and insulin dose ratio

Insulin dose		Faster aspart				Insulin aspart				Treatment ratio (means)	
		Mean		Median		Mean		Median			
		U	U/kg	U	U/kg	U	U/kg	U	U/kg	U	U/kg
Baseline	Bolus	0	0	0	0	0	0	0	0		
	Basal	52.8	0.59	50.0	0.56	51.1	0.57	46.0	0.51		
	Total	52.8	0.59	50.0	0.56	51.1	0.57	46.0	0.51		
EOT	Bolus	62.9	0.68	43.0	0.49	59.1	0.65	45.5	0.51	1.07	1.06
	Basal	51.5	0.55	48.0	0.53	49.6	0.54	42.0	0.48	1.04	1.03
	Total	114.5	1.24	95.0	1.02	108.6	1.18	91.5	1.02	1.06	1.05
EOT basal/bolus proportion of total dose		44% / 56%				44% / 56%					

Treatment ratio is faster aspart/insulin aspart. EOT, end of trial; faster aspart, fast-acting insulin aspart.

SUPPLEMENTARY DATA

Supplementary Table 6. TEAEs

	Faster aspart				Insulin aspart			
	N	**(%)**	**E**	**R**	**N**	**(%)**	**E**	**R**
All AEs	174	(51.0)	484	3.03	186	(54.5)	474	2.92
SAEs	15	(4.4)	20	0.13	24	(7.0)	31	0.19
Probably/possibly related to trial product	24	(7.0)	35	0.22	25	(7.3)	37	0.23
Recovered/resolved	149	(43.7)	355	2.22	159	(46.6)	373	2.30
Injection-site reactions	3	(0.9)	3	0.02	2	(0.6)	4	0.03
Allergic reactions	23	(6.7)	26	0.16	28	(8.2)	32	0.20

Safety analysis set: n=341 for each treatment group. An SAE was defined as any of the following: suspicion of infectious agents; death; life-threatening experience; in-patient hospitalization/prolonging of existing hospitalization; persistent or significant disability or incapacity; congenital anomaly or birth defect; or another event that, based on appropriate medical judgment, may jeopardize the subject and require medical or surgical intervention to prevent one of the outcomes listed in this definition. %, percentage of subjects; AE, adverse event; E, number of events; faster aspart, fast-acting insulin aspart; N, number of subjects; R, episodes per patient-year of exposure; SAE, serious adverse event

SUPPLEMENTARY DATA

Supplementary Table 7. Adjudicated cardiovascular events

	Faster aspart	Insulin aspart
Events sent for adjudication	13	14
Events positively adjudicated	5	7
MACE	2	4
NSTEMI	1	1
Stroke	0	1
Cardiovascular death	1	2
Not categorized as MACE	3	3

Faster aspart, fast-acting insulin aspart; MACE, major adverse cardiovascular event; NSTEMI, non-ST elevation myocardial infarction.

Supplementary Appendix

Trial inclusion criteria

1. Informed consent obtained before any trial-related activities.
2. Female or male, age ≥18 years at the time of signing of informed consent.
3. Type 2 diabetes (diagnosed clinically) ≥6 months at the time of screening.
4. Treated with basal insulin for ≥6 months prior to screening.
5. Current once-daily treatment with NPH insulin, insulin detemir, or insulin glargine for ≥3 months prior to the screening visit.
6. Current treatment with metformin (minimum dose: 1000 mg) with unchanged dosing for ≥3 months prior to screening or metformin (minimum dose: 1000 mg) in combination with sulfonylurea (SU), glinide, or dipeptidyl peptidase-4 (DPP-IV) inhibitors and/or alpha-glucosidase inhibitors (AGI) with unchanged dosing for ≥3 months prior to screening.
7. HbA_{1c} 7.0–9.5% (53–80 mmol/mol) in the metformin group at the screening visit or HbA_{1c} 7.0–9.0% (53–75 mmol/mol) in the metformin plus other oral antidiabetic agents (SU, glinide, DPP-IV inhibitors, AGI) combination group at the screening visit.
8. BMI ≤40.0 kg/m^2.
9. Ability and willingness to adhere to the protocol, including performance of self-monitored plasma glucose (SMPG) profiles.
10. Ability and willingness to eat ≥3 meals (breakfast, lunch and dinner) every day during the trial.
11. Not currently using a real-time continuous glucose-monitoring (CGM) system and/or willing not to use a real-time CGM system during the trial other than the blinded one handed out in the trial if selected to the CGM subgroup.

SUPPLEMENTARY DATA

Trial exclusion criteria

1. Any use of bolus insulin, except short-term use due to intermittent illness (no longer than 14 days of consecutive treatment) and not within 3 months prior to the screening visit.
2. Use of glucagon-like peptide-1 agonists and/or thiazolidinediones within the 3 months prior to screening.
3. Anticipated change in concomitant medication known to interfere significantly with glucose metabolism, such as systemic corticosteroids, beta-blockers, monoamine oxidase inhibitors or anti-obesity medications.
4. Cardiovascular disease within the 6 months prior to screening, defined as: stroke, decompensated heart failure New York Heart Association class III or IV, myocardial infarction, unstable angina pectoris, or coronary arterial bypass graft or angioplasty.
5. Systolic blood pressure ≥180 mmHg and/or diastolic blood pressure ≥100 mmHg after 5 min rest in a sitting position using a mean of three measurements.
6. Impaired liver function, defined as alanine transaminase ≥2.5 times upper limit of normal, according to central laboratory reference ranges.
7. Impaired renal function, defined as serum creatinine >135 μmol/L (>1.5 mg/dL) for males and >110 μmol/L (>1.2 mg/dL) for females, or estimated creatinine clearance ≤<60 mL/min, based on the Cockcroft & Gault formula and according to local practice for metformin use.
8. Recurrent severe hypoglycemia (>1 severe hypoglycemic event during the past 12 months) or hypoglycemic unawareness as judged by the investigator, or hospitalization for diabetic ketoacidosis during the 6 months prior to screening.
9. Proliferative retinopathy or maculopathy requiring treatment according to the investigator's judgement.
10. Females of childbearing potential who are pregnant, breast-feeding or intending to become pregnant or are not using adequate contraceptive methods.
11. Any clinically significant disease or disorder, except for conditions associated with type 2 diabetes, which in the investigator's opinion might jeopardize subject's safety or compliance with the protocol.
12. Any condition that the investigator judges would interfere with evaluation of the results.
13. A life-threatening disease, including malignant neoplasms and medical history of malignant neoplasms within the last 5 years (except basal and squamous cell skin cancer) prior to screening.
14. Mental incapacity, psychiatric disorder, unwillingness or language barriers precluding adequate understanding or co-operation as judged by the investigator, including being unable to read or write.
15. Previous participation in this trial, defined as inclusion in the run-in period (Visit 2).
16. Known or suspected hypersensitivity to trial products or related products.
17. Receipt of any investigational medicinal product within 1 month prior to screening.
18. Donation of blood within 1 month prior to screening.
19. Known or suspected abuse of alcohol, narcotics or illicit drugs.

Supplementary statistical material

Treatment-emergent adverse events

Treatment-emergent adverse events (TEAEs) were summarized by seriousness, severity, and relation to insulin treatment. Injection-site reactions, allergic reactions, cardiovascular events sent for adjudication, dose reduction due to AEs, withdrawal due to AEs and outcomes were summarized by treatment.

The number of treatment-emergent severe or blood glucose (BG) confirmed hypoglycemic episodes from baseline to Week 26 were analyzed using a negative binomial regression model with a log–link function and the logarithm of the time period for which a hypoglycemic episode was considered treatment-emergent as offset. The model included treatment, CGM strata and region as factors. Separate analyses were made for treatment-emergent severe or BG confirmed hypoglycemic episodes in relation to time since start of meal (1, 2, 4 and 6 hours following start of meal, respectively) and time of day (daytime/nocturnal).

Sample size and power determination

Sample size and power was determined for the primary endpoint using a *t*-statistic with the assumption of a one-sided test of 2.5% and a zero mean treatment difference. Based on previous phase 3 trials in subjects with type 2 diabetes treated with insulin aspart, a conservative estimate for the standard deviation of 1.2% for change from baseline in HbA_{1c} was used in the sample-size calculation. For determination of power in the second step, a *t*-statistic with a two-sided test of size 5.0% was used, expecting the treatment difference to be at least 1.0 mmol/L. The sample size calculation was performed using proc power in SAS 9.1.3.

Secondary efficacy endpoints

HbA_{1c} responder endpoints after 26 weeks of treatment were based on a logistic regression model using treatment, CGM strata and region as factors, and baseline HbA_{1c} as a covariate. For subjects without an HbA_{1c} measurement at Week 26, the predicted values from a mixed-effect model for repeated measures (MMRM) similar to those for the primary analysis were used.

Change from baseline in 2-h postprandial glucose (PPG) increment (meal test) after 26 weeks of treatment was analyzed based on the laboratory measured values in the meal test and analyzed using an analysis of variance (ANOVA) model including treatment, CGM strata and region as factors, and with 2-h PPG increment at baseline as covariate.

The 1-, 2-, 3- and 4-h PPG and PPG increment changes from baseline after 26 weeks of treatment were analyzed separately using an ANOVA model including treatment, CGM strata, and region as factors, and the corresponding baseline PPG or PPG increment as covariate.

Change from baseline in mean of the 7-9-7-point SMPG profile after 26 weeks of treatment was analyzed based on measurements at visits 22 and 36 using an MMRM similar to that used for the primary endpoint, except with the corresponding baseline value as covariate.

Changes from baseline in PPG increment endpoints (mean and each separate meal) were analyzed based on measurements at visits 22 and 36 using an MMRM similar to the model used for analysis of the primary endpoint except with the corresponding baseline value as covariate. PPG responder endpoints after 26 weeks of treatment were based on a logistic regression model using treatment, CGM strata and region as factors, and baseline overall mean 2-h PPG as a covariate. For subjects without a mean 2-h PPG measurement at Week 26, the predicted values from a MMRM similar to that for the primary analysis were used.

Body weight and fasting plasma glucose (FPG) changes from baseline after 26 weeks of treatment were analyzed based on measurements at visits 22 and 36 using an MMRM similar

to that used for analysis of the primary endpoint but with body weight or FPG at baseline as covariate.

Change from baseline in 1,5-AG after 26 weeks of treatment was analyzed based on measurements at visits 14, 18, 22, 26, 30 and 36 using an MMRM similar to that used for analysis of the primary endpoint except with baseline 1,5-AG as covariate.

Insulin doses were summarized descriptively by treatment week according to regimen, both by time point of administration and as total daily dose in units and units/kg.

SUPPLEMENTARY DATA

List of participating investigators

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