

SUPPLEMENTARY DATA

Supplementary Table 1. Titration table for basal insulin

FPG (mean of 3 consecutive days)		Adjustment of IDeg or IGl _{ar} (U)
mmol/l	mg/dl	
<3.1	<56	-4 (if dose >45 U, reduce by 10%)
<3.9	56–69	-2 (if dose >45 U, reduce by 5%)
<5.0	70–89	0
<7.0	90–125	+2
<8.0	126–143	+4
<9.0	144–161	+6
≥9.0	≥162	+8

FPG, fasting plasma glucose; IDeg, insulin degludec 200 U/ml; IGl_{ar}, insulin glargine

Supplementary Table 2. Most frequent (≥5%) treatment-emergent adverse events

	IDeg 200 U/ml OD				IGlar OD			
	N = 228				N = 228			
	n	%	E	R	n	%	E	R
Events	51	22.4	76	72	60	26.3	89	83
Nervous system disorders								
Headaches	20	8.8	27	26	24	10.5	36	34
Infections and infestations								
Nasopharyngitis	17	7.5	18	17	12	5.3	13	12
Upper respiratory tract infection	7	3.1	7	7	15	6.6	18	17
Gastrointestinal disorders								
Diarrhea	17	7.5	24	23	19	8.3	22	21

E, number of events; IDeg 200 U/ml, insulin degludec 200 U/ml; IGl_{ar}, insulin glargine; N, number of patients in the analysis; n, number of patients with events; OD, once-daily; R, rate per 100 exposure years

Supplementary Table 3. Adverse events leading to withdrawal

Treatment	Adverse event
IGlar, n = 4	Myocardial ischemia, ischemic stroke, hypercalcemia & renal failure (acute), pneumonia
IDeg 200 U/ml, n = 5	Laryngeal cancer, abdominal distension, drug-dispensing error, colon cancer, lung neoplasm (malignant)

IDeg 200 U/ml, insulin degludec 200 U/ml; IGl_{ar}, insulin glargine

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Supplementary Table 4. Event rate of serious adverse events

SAE by system organ class	IDeg 200 U/ml OD				IGlar OD			
	N = 228				N = 228			
	n	%	E	R	n	%	E	R
All serious AEs	15	6.6	23	22	10	4.4	14	13
Infections and infestations	4	1.8	5	5	2	0.9	2	2
Cardiac disorders	3	1.3	4	4	2	0.9	2	2
General disorders and administration-site conditions	5	2.2	5	5	0	0	0	0
Neoplasms, benign, malignant and unspecified	3	1.3	3	3	1	0.4	1	1
Musculoskeletal and connective tissue disorders	2	0.9	2	2	1	0.4	1	1
Gastrointestinal disorders	1	0.4	1	1	1	0.4	1	1
Injury, poisoning and procedural complications	1	0.4	1	1	1	0.4	1	1
Metabolism and nutrition disorders	0	0	0	0	2	0.9	2	2
Renal and urinary disorders	0	0	0	0	2	0.9	2	2
Nervous system disorders	0	0	0	0	1	0.4	1	1
Psychiatric disorders	1	0.4	1	1	0	0	0	0
Respiratory, thoracic and mediastinal disorders	0	0	0	0	1	0.4	1	1
Vascular disorders	1	0.4	1	1	0	0	0	0

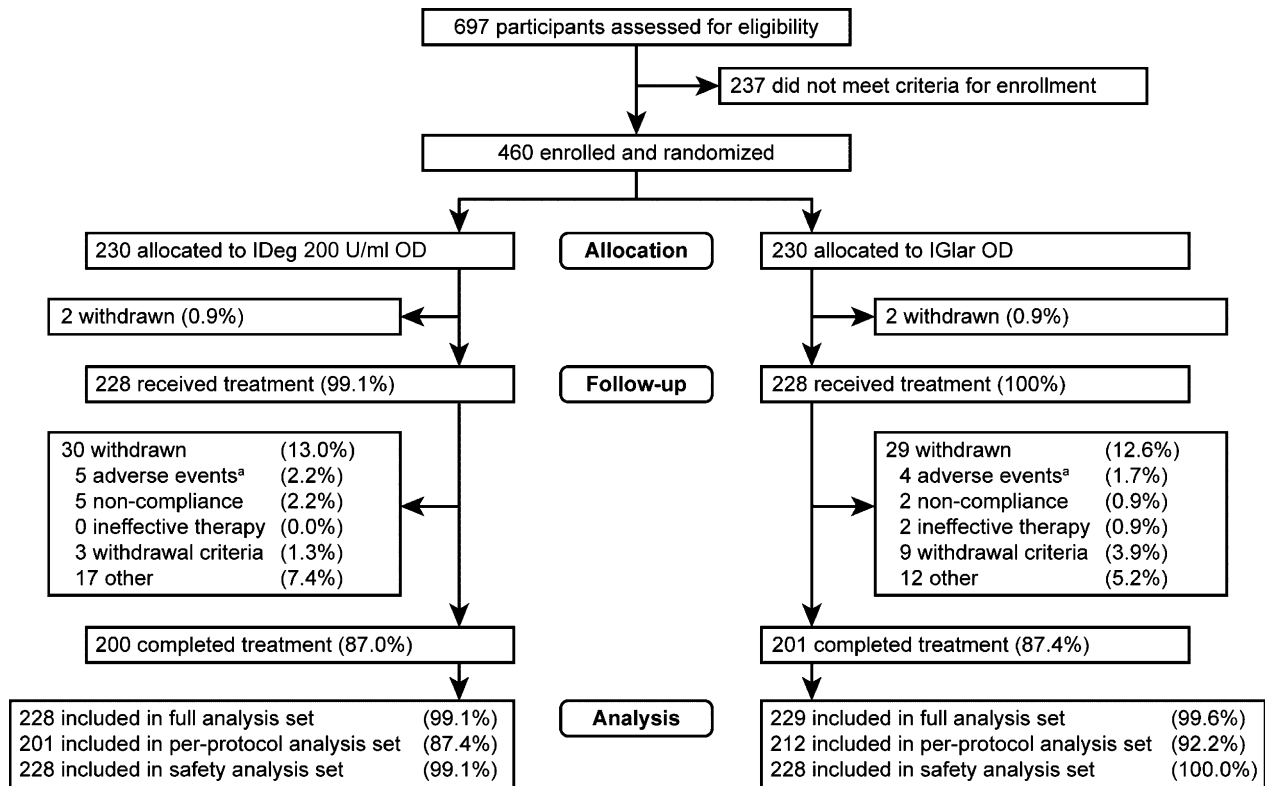
AE, adverse event; e, number of events; IDeg 200 U/ml, insulin degludec 200 U/ml; IGlar, insulin glargine; N, number of patients in the analysis; n, number of participants with events; OD, once-daily; R, rate per 100 patient-years of exposure; SAE, serious adverse event; %, proportion of participants with episodes

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Supplementary Table 5. List of principal investigators

Country	Investigator
Canada	R.H. Tytus, R. Somani, S. Wharton, J.F. Liutkis, F. Blouin, DeYoung, Z. Punthakee, E. Raff, W. Rosenthal, S.A. Ross, S. Syan
France	R. Mira, J-P. Donnet, J-P. Courreges, A. Penfornis, P. Serusclat, E. Ghanassia, Y. Lorcy
Ireland	J. Nolan, S. Sreenan, B. Kinsley
Russia	E. Zhdanova, I. Zakharyan, A. Mayorov, V. Potin, E. Rechkova, N. Trelskaya, T. Raskina
South Africa	G. Podgorski, J.A. Kok, A. Amod, L. JamJam
Ukraine	L. Sokolova, V. Korpachev
United Kingdom	M. Gibson, K. Adamson, D. Bhatnagar, C.R. Bundy, I. Caldwell, P. Saul, B. Silvert, A. Collier, I. Malik, P. Evans, R. Falk, M. Linton, N. Taylor, N. Geonka, T. Gooding, P. Goulden, J.N. Harvey, E. Jude, S. Kumar, P. O'hare, I. Parker, S. Rajbhandari, F. Raymond, J. Saunders
United States	J. Buse, R. Bergenstal, K. Furlong, G. Griffing, J. Albu, J. Rudolph, M. Sheikh-Ali, K. Tolia, T. Bauch, G. Bedel, E. Cheng, M. Christiansen, F. Fusco, W. Gonte, S. Herrington, R. Jain, S. Lerman, H. Maheshwari, M. McDermott, R. Nelson, O. Odugbesan, C. Pinner, J. Reed, L. Schmidt, R.B. Scott, R. Tamayo, I. Tandon, P. Winkle, O. Brusco, M. Cooperman, M. Diodato, M. Mach, M. Murdock, L. Phillips, A. Bhargava, J. Unger, M. Bari, E. Kwon, S. Elliott, S. Bhuchar, A. Ahmed, L. Lamarre, J. Risser, N. Fraser, A. Khan, R. Madder, S. Rovner, D. Webster, J. Covalesky, M. Quadrel, L. Feld, P. Rosenblit, L. Klaff, J. Frame, D. Felker, W. Lasswell Jr., A. Murray, M. Rothberg, F. Jimenez, M. Acampora, M. Mikhail, E. Schramm, M. Kutner, R. Samaan

Supplementary Figure 1. Subject disposition

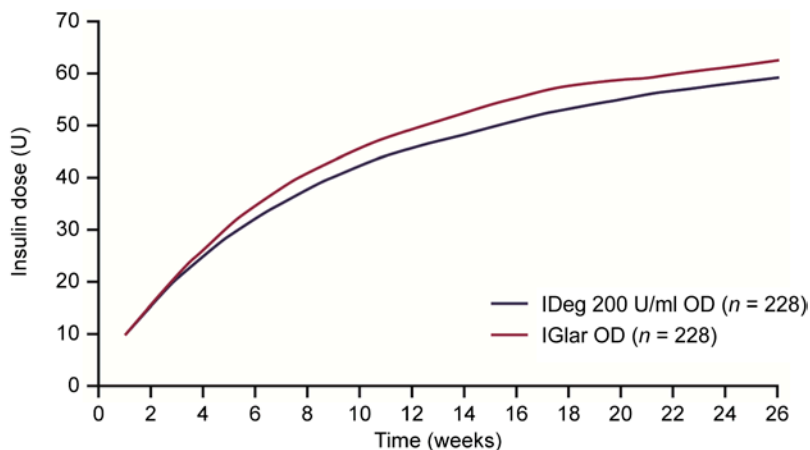


^aAdverse events leading to withdrawal are described in Supplementary Table 2.

Full analysis set (FAS): all randomized participants, i.e., intent-to-treat population; safety analysis set (SAS): participants exposed to treatment; per-protocol (PP) analysis set: participants with exposure to treatment for at least 12 weeks with a valid HbA_{1c} assessment at baseline and at or after 12 weeks, and without any violations of inclusion or exclusion criteria.

IDeg 200 U/ml, insulin degludec 200 U/ml; IGlar, insulin glargine; OD, once-daily

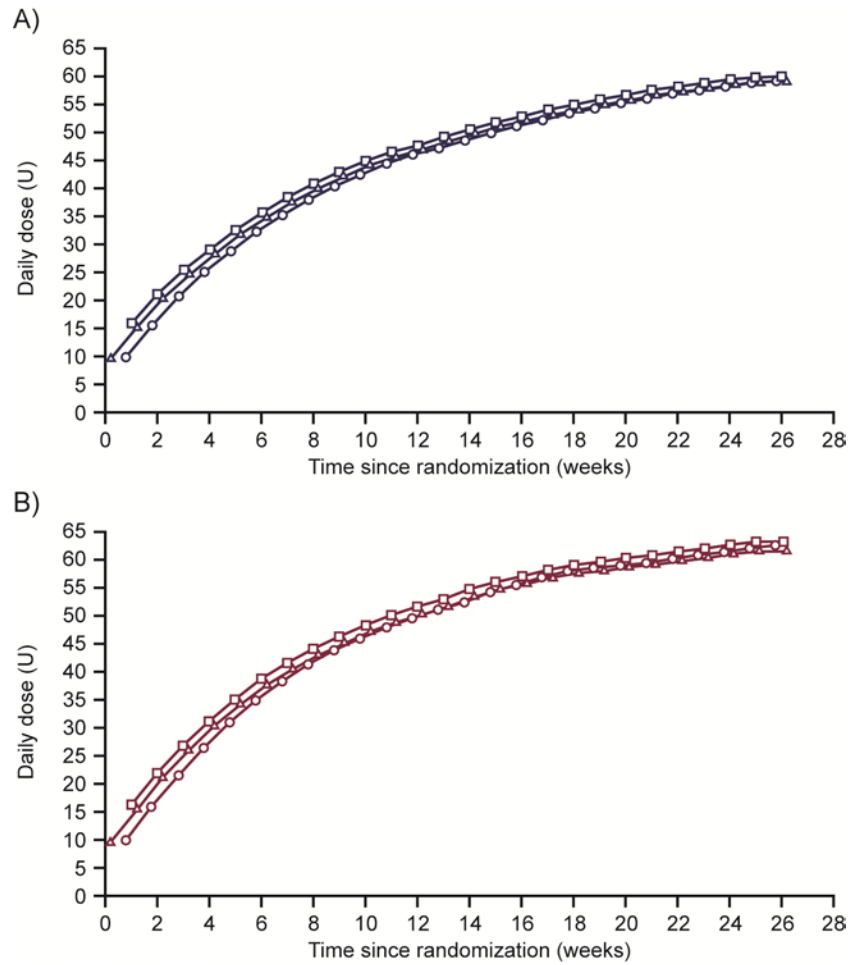
Supplementary Figure 2. Daily basal insulin dose over time.



IDeg 200 U/ml, insulin degludec 200 U/ml; IGlar, insulin glargine; OD, once-daily

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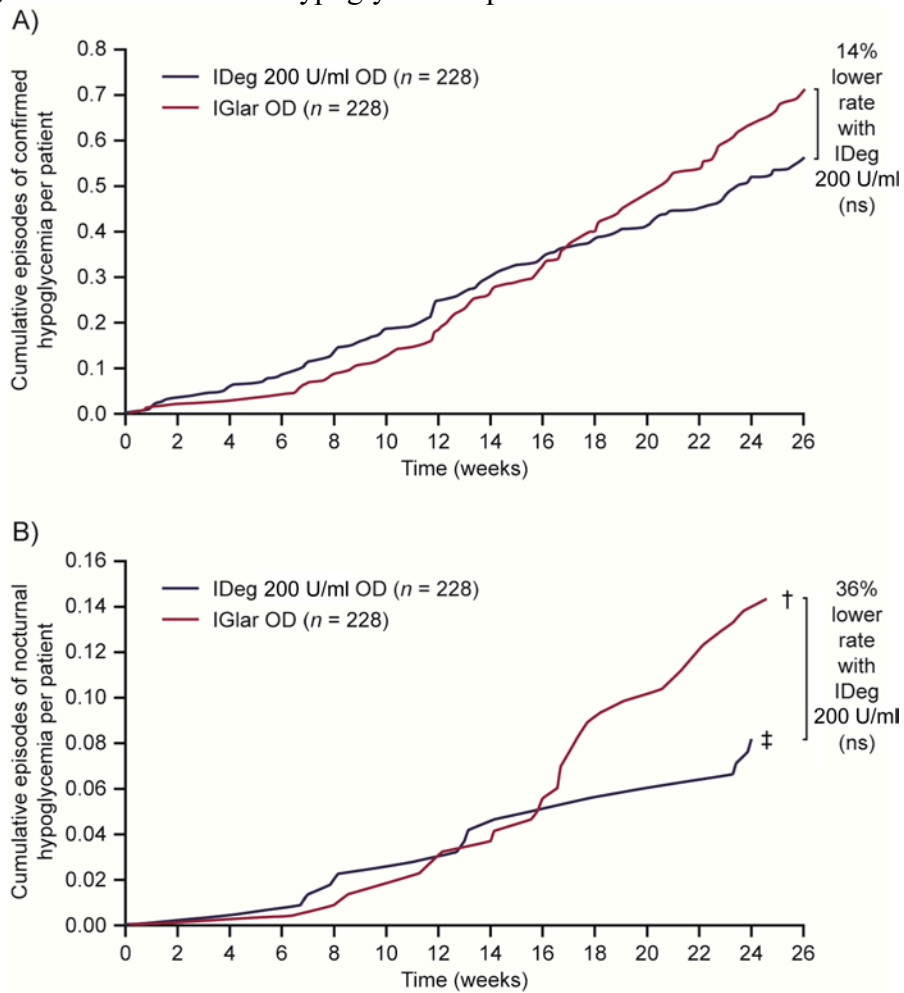
Supplementary Figure 3. Prescribed, actual, and titration algorithm dose in units for A) IDeg 200 U/ml and B) IGLar. Open circle = daily actual insulin dose; open triangle = daily prescribed insulin dose; open square = daily algorithm insulin dose.



IDeg 200 U/ml, insulin degludec 200 U/ml; IGLar, insulin glargine

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Supplementary Figure 4. Cumulative number of hypoglycemic episodes per patient for A) overall confirmed and B) nocturnal confirmed hypoglycemic episodes.



†No nocturnal confirmed hypoglycemic episodes occurred after week 25 in the IGlar group.
‡No nocturnal confirmed hypoglycemic episodes occurred after week 24 in the IDeg 200 U/ml group.
IDeg 200 U/ml, insulin degludec 200 U/ml; IGlar, insulin glargine; ns, not significant; OD, once-daily