SUPPLEMENTARY DATA

Supplementary Table 1. Mean Total Daily Aspart Doses per Meal

			Breakfast	Lunch	Main evening meal
Visit	**Unit**	**Treatment**	**Mean**	**Mean**	**Mean**
Baseline	U	IDegAsp	9.85	10.05	11.10
		IDet	8.75	9.44	10.55
	U/kg	IDegAsp	0.13	0.13	0.14
		IDet	0.12	0.12	0.14
End of trial	U	IDegAsp	12.27	13.75	13.22
		IDet	12.60	14.22	15.44
	U/kg	IDegAsp	0.15	0.17	0.16
		IDet	0.16	0.18	0.20

Supplementary Table 2. Hypoglycemia data

	IDegAsp OD (*n* = 362)				**IDet (*n* = 180)**					
	Patients		**Events**	**Rate**	**Patients**		**Events**	**Rate**	**Rate ratio**	***P*-values**
	n	**%**	***n***	**per PYE**	***n***	**%**	***n***	**per PYE**	**IDegAsp/IDet [95% CI]**	
Severe	35	9.7	56	0.33	22	12.2	35	0.42	1.19 [0.58; 2.41]	NS
Confirmed	341	94.2	6634	39.17	168	93.3	3720	44.34	0.91 [0.76; 1.09]	NS
Nocturnal	192	53.0	629	3.71	125	69.4	480	5.72	0.63 [0.49; 0.81]	$P < 0.05$

CI, confidence interval; IDegAsp, insulin degludec/insulin aspart; IDet, insulin detemir; NS, not significant; OD, once daily; PYE, patient-year of exposure

SUPPLEMENTARY DATA

Supplementary Table 3. Adverse event rate data

	IDegAsp OD	**IDet**
All patients	362	180
Patients with events	239	114
Percentage of patients with events	66.0%	63.3%
Number of events	846	436
Adverse event rate per PYE	**5.00**	**5.20**
Number of patients with serious AEs	31	13
Percentage of patients with serious AEs	8.6%	7.2%
Number of events	46	17
Serious adverse event rate per PYE	**0.27**	**0.20**
Number of patients withdrawn due to AEs	4	3
Percentage of randomized patients withdrawn	1.1%	1.6%

AE, adverse event; IDegAsp, insulin degludec/insulin aspart; IDet, insulin detemir; OD, once daily; PYE, patient-year of exposure

SUPPLEMENTARY DATA

Supplementary Table 4. Adverse events reported with an incidence ≥5% patients

	IDegAsp OD ***n*** **= 362**				**IDet** ***n*** **= 180**			
	n	**%**	**Events**	**Rate**	***n***	**%**	**Events**	**Rate**
Events	130	35.9	287	1.69	71	39.4	129	1.54
Infections and infestations								
Nasopharyngitis	78	21.5	111	0.66	32	17.8	44	0.52
Upper respiratory tract infection	24	6.6	33	0.19	16	8.9	26	0.31
Nervous system disorders								
Headache	27	7.5	83	0.49	15	8.3	18	0.21
Gastrointestinal disorders								
Diarrhea	10	2.8	11	0.06	9	5.0	9	0.11
Metabolism and nutrition disorders								
Hypoglycemia	33	9.1	49	0.29	22	12.2	32	0.38

IDegAsp, insulin degludec/insulin aspart; IDet, insulin detemir; OD, once daily

SUPPLEMENTARY DATA

Supplementary Table 5. Serious adverse events possibly/probably related to trial therapy

	IDegAsp OD *n* = 362				**IDet *n* = 180**			
	n	**%**	**Events**	**Rate**	***n***	**%**	**Events**	**Rate**
Events	15	4.1	25	0.15	5	2.8	7	0.08
Metabolism and nutrition disorders								
Hypoglycemia	10	2.8	18	0.11	4	2.2	4	0.05
Hypoglycemic unconsciousness	4	1.1	4	0.02	2	1.1	2	0.02
Hypoglycemic seizure	1	0.3	1	0.01	1	0.6	1	0.01
Injury, poisoning and procedural complications								
Wrong drug administered	2	0.6	2	0.01	0	0.0	0	0.00

IDegAsp, insulin degludec/insulin aspart; IDet, insulin detemir; OD, once daily

S6. List of principal investigators

Australia: Geoffrey Nicholson, Anthony Roberts, Richard Simpson, Sultan Linjawi, David O'Neal, Glynis Ross, Thomas Donnelly
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United States: Bruce Bode, Jolene Berg, Stephen Cohen, Angel Comulada-Rivera, Robert Cuddihy, Anthony Dulgeroff, Raymond Fink, David Fitz-Patrick, Gregg Gerety, Janice Gilden, J Michael Gonzalez-Campoy, Irl Hirsch, Allen King, Elise Kwon, William Litchfield, Kathryn Lucas, Minh Mach, Lyle Myers, Ola Odugbesan, John Pullman, Maria Ramos-Roman, John Reed, Bradd Silver, Teresa Sligh, Peter Weissman

SUPPLEMENTARY DATA

S7. CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item no.	Checklist item	Reported on page no.
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4–6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6, 7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8, 9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9, 10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
equence generation	8a	Method used to generate the random allocation sequence	7, 8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7, 8
location 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	7, 8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7, 8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	7, 8
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10, 11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10, 11
Results			

SUPPLEMENTARY DATA

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	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
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)	11–15, Figs 2 + 3, Suppl. Table 1 + 2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	11–15
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	15, Suppl. Tables S3–5
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15–18
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	15–18
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15–18
Other information			
Registration	23	Registration number and name of trial registry	2, 6
Protocol	24	Where the full trial protocol can be accessed, if available	The full protocol is not publicly available but can be supplied on request.
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	18

*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.