

Table A. Baseline characteristics of the people with type 2 diabetes studied (ITT population).

	Insulin detemir	NPH insulin
Number randomized (n)	237	238
Sex (M/F %)	49.4 / 50.6	56.7 / 43.3
Ethnic origin (n) (black/white/Asian/other)	1/232/4/0	0/237/0/1
Age (years)	61.3 (9.1) 40–80	60.4 (9.3) 27–79
Weight (kg)	82.7 (13.3) 44–128	82.5 (14.2) 42.2–126
BMI (kg/m ²)	28.9 (3.6) 18.1–35.7	29.0 (3.6) 18.3–35.6
Duration of diabetes (years)	9.6 (6.6) 1–40	9.8 (6.2) 1–36
Complications (%)		
retinopathy	10	9
neuropathy	17	16
nephropathy	5	7
macroangiopathy	27	22
HbA _{1c} (%)	8.61 (0.78) 7.0–10.3	8.51 (0.76) 6.2–10.4
OGLD use (%)		
metformin alone	5.9	8.0
secretagogue alone	28.7	26.5
acarbose alone	–	0.4
combination therapy	65.4	65.1

Data are n, % or mean (SD) range.

OGLD, oral glucose-lowering drug

HbA_{1c} reference range <6.1 %

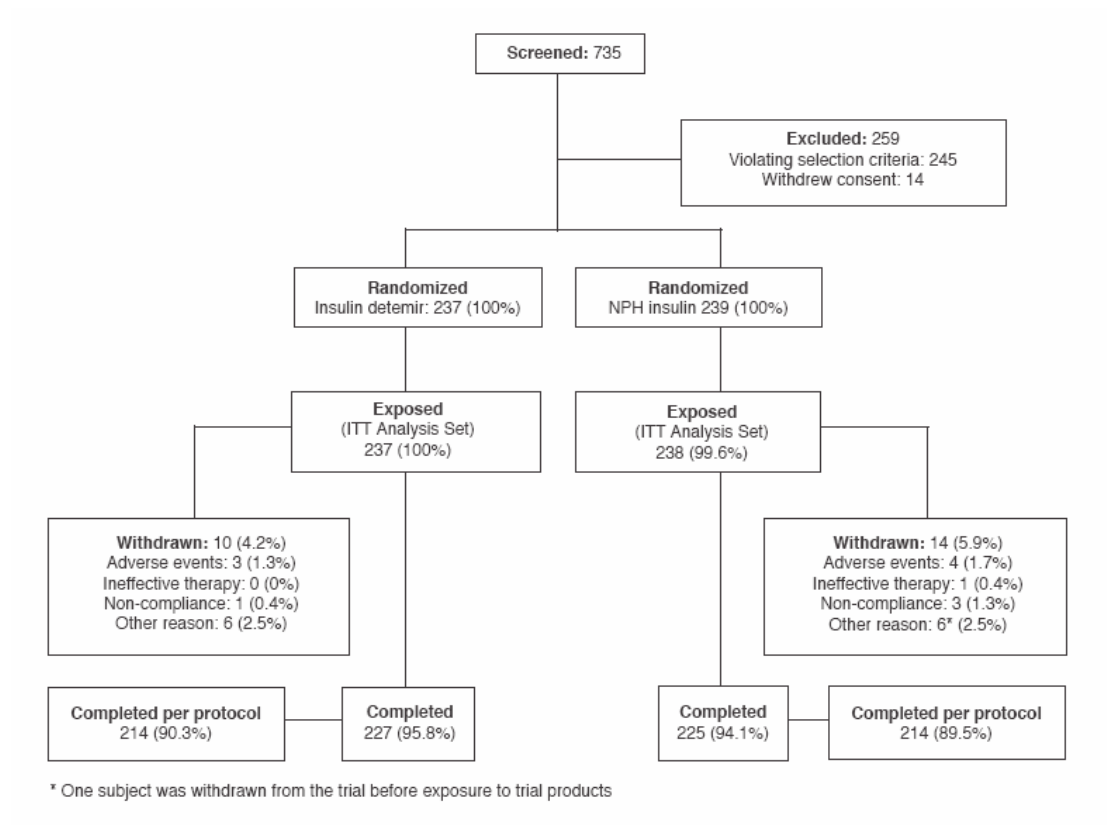
Table B. Hypoglycemia episodes and relative risk of hypoglycemia.

Episode	Insulin detemir			NPH insulin			Relative risk RR [95% CI])	p
	n=237			n=238				
	patients n (%)	events n	events/ pt.-year	patients n (%)	events n	events/ pt.-year		
All								
any	151 (64)	908	8.60	191 (80)	1688	15.96	0.53 [0.42–0.68]	<0.001
minor	96 (41)	387	3.67	153 (64)	755	7.14	0.48 [0.35–0.65]	<0.001
symptoms only	124 (52)	519	4.92	160 (67)	923	8.73	0.56 [0.42–0.74]	<0.001
major	1 (0)	1	0.01	6 (3)	8	0.08	– ^a	–
Nocturnal								
any	71 (30)	160	1.52	112 (47)	349	3.30	0.45 [0.32–0.64]	<0.001
minor	40 (17)	74	0.70	84 (35)	187	1.77	0.39 [0.26–0.58]	<0.001
symptoms only	51 (22)	86	0.81	59 (25)	161	1.52	0.54 [0.34–0.85]	0.008
major	0 (0)	0	0.00	1 (0)	1	0.01	– ^a	–

‘Minor’ episodes are episodes not requiring assistance and confirmed by capillary plasma glucose measurement (<3.1 mmol/L). ‘Symptoms only’ are reported episodes for which either no plasma glucose measurement was taken or where the plasma glucose value was ≥3.1 mmol/L.

^a*relative risk not calculated because of small numbers*

Figure A. Patient disposition during study



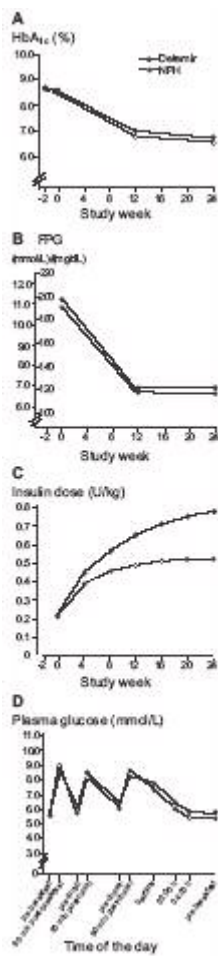


Figure B. Glycemic control and dose:

A) Change in HbA_{1c} over time

B) Change in FPG over time

C) Change in dose over time

D) Participant-measured plasma glucose profiles after 24 weeks' treatment with insulin detemir and NPH insulin. Measurements were made at 10 time points, including breakfast the following day. Data contribution cohort: Insulin detemir, n=224; NPH insulin, n=223. Data are estimated means. All SE values <0.19 mmol/L.

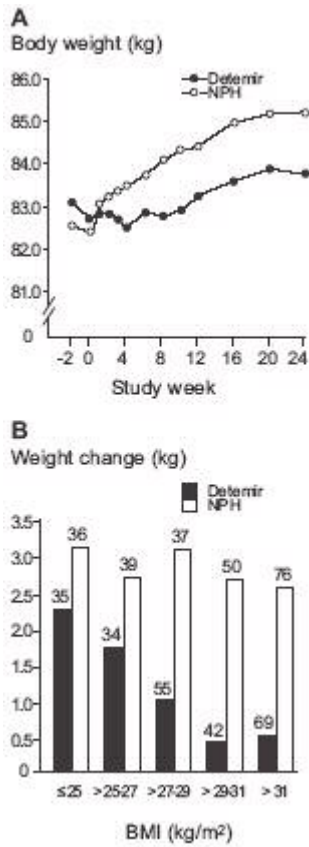


Figure C. Body weight change

A) Mean body weight with time of study on insulin detemir and NPH insulin. Baseline adjusted weight was statistically different ($p < 0.001$ – see text) at 24 weeks.

B) Change in mean body weight by treatment group stratified by baseline BMI. Numbers over bars are number of participants.

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