SUPPLEMENTARY DATA

Further statistical analysis details

Comparison of subjects who achieved target A1C ≤6.0% at both 24 and 36 gestational weeks (GWs) was made with logistic regression, using the same factors and covariates as for the primary endpoint. Superiority was tested. Analysis of fasting plasma glucose (FPG) at 24 and 36 GWs was made separately using a normal linear regression model with treatment, country, and pregnancy status at randomization as factors, and FPG at randomization and the FPG at randomization by pregnancy status at randomization interaction as covariates. Superiority was tested for FPG. Analysis of the 8-point self-monitored plasma glucose (SMPG) profiles at 24 GWs was made using a linear mixed model where time point (i.e., time of measurement during the day) was the repeated measurement within a subject. The fixed factors in the model were treatment, time point, country, time point by treatment interaction, and pregnancy status at randomization. An unstructured covariance matrix was applied. The individual profiles were tested to see if they were parallel (considered to exist if the interaction between time and treatment was non-significant), in which case the model was reduced by omitting the interaction term. . Analysis of 8-point SMPG at 36 GWs was made using the same model, except that a compound symmetry covariance matrix was applied (due to lack of convergence when using an unstructured covariance matrix).

Supplementary Table 1. Algorithm for titration of basal insulin dose

Current basal dose		Pre-pregnant or <20 GWs	≥20 GWs
FPG or pre-dinner plasma glucose		Adjustment (U)	
<4.0 mmol/l	<72 mg/dl	Reduce according to local practice	Reduce according to local practice
4.0–6.0 mmol/l	72–108 mg/dl	0	0
6.1–8.0 mmol/l	109–144 mg/dl	+1	+2
>8.0 mmol/l	>144 mg/dl	+2	+4

Abbreviations**:** FPG = fasting plasma glucose; GW = gestational week; U = units

Supplementary Table 2. Algorithm for titration of bolus insulin dose

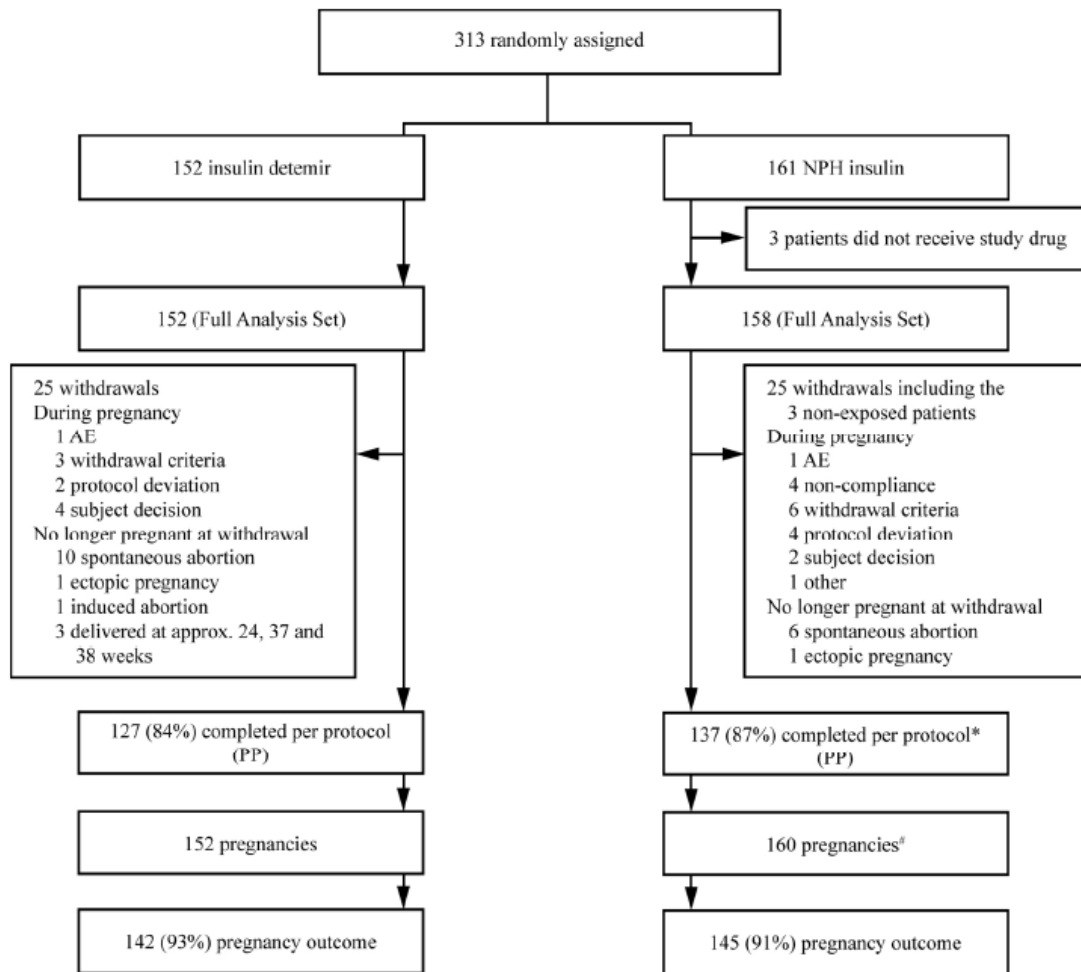| Current bolus dose		Pre-pregnant or <20 GWs	≥20 GWs
Postprandial plasma glucose		Adjustment (U)	
<4.0 mmol/l	<72 mg/dl	Reduce according to local practice	Reduce according to local practice
4.0–7.0 mmol/l	72–126 mg/dl	0	0
7.1–10.0 mmol/l	127–180 mg/dl	+1	+2
>10.0 mmol/l	>180 mg/dl	+2	+4

Abbreviations: GW = gestational week; U = units

SUPPLEMENTARY DATA

Supplementary Table 3. Maternal serious adverse events. E=events; R=rate (per 100 patient-year).

System organ class	IDet				NPH			
	N	%	E	R	N	%	E	R
All subjects	152				158			
Exposure (year)	82.4				86.3			
Events	61	40.1	94	114.1	49	31.0	76	88.1
Pregnancy, puerperium and perinatal conditions	39	25.7	39	47.3	26	16.5	31	35.9
Metabolism and nutrition disorders	17	11.2	19	23.1	13	8.2	22	25.5
Gastrointestinal disorders	5	3.3	10	12.1	4	2.5	8	9.3
Infections and infestations	7	4.6	7	8.5	2	1.3	2	2.3
Reproductive system and breast disorders	3	2.0	3	3.6	5	3.2	5	5.8
Nervous system disorders	4	2.6	4	4.9	2	1.3	2	2.3
Vascular disorders	2	1.3	3	3.6	1	0.6	1	1.2
Injury, poisoning and procedural complications					2	1.3	3	3.5
Eye disorders	2	1.3	2	2.4				
General disorders and administration site conditions	2	1.3	2	2.4				
Hepatobiliary disorders	2	1.3	2	2.4				
Social circumstances	1	0.7	1	1.2	1	0.6	1	1.2
Investigations	1	0.7	1	1.2				
Renal and urinary disorders	1	0.7	1	1.2				
Skin and subcutaneous tissue disorders					1	0.6	1	1.2

Supplementary Figure 1. Patient flow diagram


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                        ┌─────────────────────────────┐
                        │   313 randomly assigned     │
                        └─────────────────────────────┘
```

313 randomly assigned

152 insulin detemir | 161 NPH insulin

3 patients did not receive study drug

152 (Full Analysis Set) | 158 (Full Analysis Set)

25 withdrawals
During pregnancy
  1 AE
  3 withdrawal criteria
  2 protocol deviation
  4 subject decision
No longer pregnant at withdrawal
  10 spontaneous abortion
  1 ectopic pregnancy
  1 induced abortion
  3 delivered at approx. 24, 37 and
    38 weeks

25 withdrawals including the
  3 non-exposed patients
During pregnancy
  1 AE
  4 non-compliance
  6 withdrawal criteria
  4 protocol deviation
  2 subject decision
  1 other
No longer pregnant at withdrawal
  6 spontaneous abortion
  1 ectopic pregnancy

127 (84%) completed per protocol (PP) | 137 (87%) completed per protocol* (PP)

152 pregnancies | 160 pregnancies#

142 (93%) pregnancy outcome | 145 (91%) pregnancy outcome
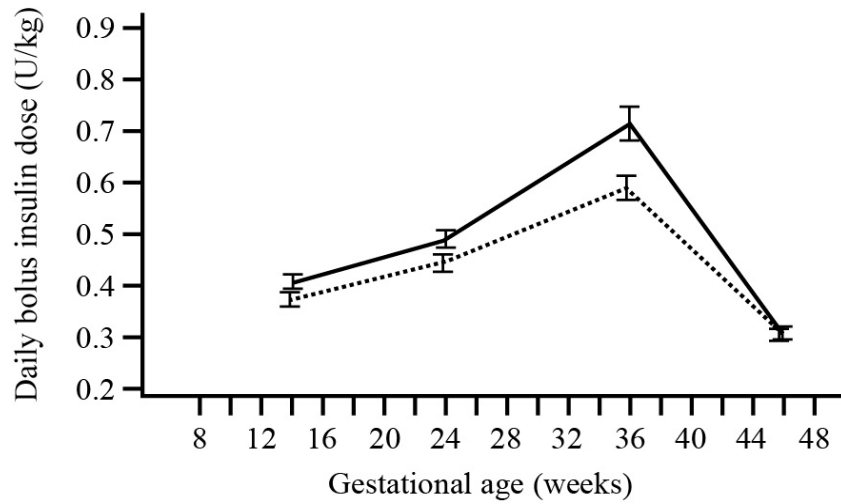
*one non-completer was included in the PP analysis as withdrawal was after 32 weeks of pregnancy.
#two subjects stayed in the trial following spontaneous abortions.

SUPPLEMENTARY DATA

Supplementary Figure 2. Bolus insulin dose: mean (□SEM) during pregnancy and at follow-up.
Abbreviations**:** NPH = neutral protamine Hagedorn; SEM, standard error of the mean.
Key**:** Detemir = solid line; NPH = dotted line

SupplementaryFigure 3. Basal insulin dose: mean (±SEM) during pregnancy and at follow-up.
Abbreviations**:** NPH = neutral protamine Hagedorn; SEM, standard error of the mean.
Key**:** Detemir = solid line; NPH = dotted line