Supplementary Figure 1. Subject disposition.

*Two subjects stayed in the trial following spontaneous abortions.

AE, adverse event.

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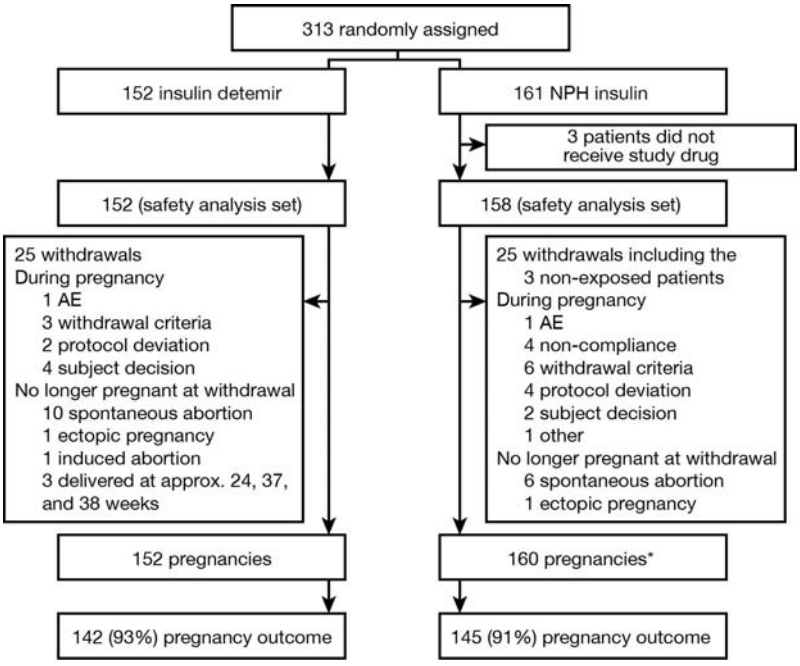

Supplementary Table I. Clinical characteristics at baseline prior to start of study drug.

Characteristic	IDet	NPH
Randomized and exposed	152	158
Randomized during early pregnancy, *n* (%)	79 (52.0)	83 (52.5)
Randomized before pregnancy, *n* (%)	73 (48.0)	75 (47.5)
Age, years	29.7 (4.6)	30.4 (4.2)
BMI, kg/m^2	24.3 (4.0)	25.2 (4.2)
Duration of diabetes, years	11.7 (8.1)	12.8 (7.9)
A1C, %	6.95 (0.82)	7.08 (0.76)
FPG, mg/dL	106.0 (59.2)	107.8 (58.1)
FPG, mmol/L	5.9 (3.3)	6.0 (3.2)
Retinopathy, n (%)	43 (28.3)	40 (25.3)
Smoker, n (%)	9 (5.9)	11 (7.0)

Values are mean (SD) or numbers (%).

A1C, glycated hemoglobin; FPG, fasting plasma glucose; IDet, insulin detemir; NPH, neutral protamine Hagedorn.

Supplementary Table II. Mode of delivery.

Characteristic	**IDet**		**NPH**	
	n	**%**	***n***	**%**
Pregnancy outcomes at follow-up	142	–	145	–
Live births	128	–	136	–
Mode of delivery	130	100%*	136	100%
Spontaneous onset of labor	25	19%	38	28%
Induction of labor	50	38%	49	36%
Vaginal delivery	54	42%	50	37%
Instrumental (calculated from vaginal deliveries)	*13*	*24%*	*10*	*20%*
Elective caesarean section	49	38%	49	36%
Emergency caesarean section	27	21%	37	27%

Values are numbers (%).

* 2 stillbirths are included in the IDet group.

IDet, insulin detemir; NPH, neutral protamine Hagedorn.

Supplementary Table III. Summary of adverse, serious, and severe adverse events in the offspring.

		IDet			NPH		
		n	**%**	**Episodes/ child**	***n***	**%**	**Episodes/ child**
All AEs	All	56	36.8	2.2	55	34.8	2.8
	Pregnant at randomization	33	41.8	1.8	29	34.9	2.6
	Pregnant after randomization	23	31.5	2.6	26	34.7	3.0
Serious AEs	All	36	23.7	1.4	32	20.3	1.7
	Pregnant at randomization	20	25.3	1.4	17	20.5	1.9
	Pregnant after randomization	16	21.9	1.4	15	20.0	1.3
Severe AEs	All	15	9.9	1.1	12	7.6	1.8
	Pregnant at randomization	5	6.3	1.0	7	8.4	1.0
	Pregnant after randomization	10	13.7	1.2	5	6.7	1.6
AEs possibly/probably related to basal insulin*	All	1	0.7	1.0	0	0.0	0.0
	Pregnant at randomization	1	1.3	1.0	0	0.0	0.0
	Pregnant after randomization	0	0.0	0.0	0	0.0	0.0
AEs possibly/probably related to bolus insulin*	All	1	0.7	1.0	0	0.0	0.0

	Pregnant at randomization	1	1.3	1.0	0	0.0	0.0
	Pregnant after randomization	0	0.0	0.0	0	0.0	0.0
AEs leading to withdrawal	All	0	0.0	0.0	1	0.6	1.0
	Pregnant at randomization	0	0.0	0.0	0	0.0	0.0
	Pregnant after randomization	0	0.0	0.0	1	1.3	1.0

* This case of fetal distress was detected by an antenatal non-stress test (cardiotocography) performed due to maternal pruritus and elevated liver enzymes (hepatic cytolysis) at GW 36+2 days. The child was born healthy by caesarean section, with an Apgar score of 10 at 1 minute after birth, and was considered recovered on the same day. The mother temporarily discontinued use of insulin detemir for 1 day after which the insulin was reintroduced. Mother and child were discharged from the hospital 1 week after delivery. At the follow-up examination the mother was considered fully recovered. The event was considered by the investigator to be possibly or probably related to both the basal and bolus insulins, but an alternative aetiology of the mother´s liver dysfunction was also provided. A full evaluation by the safety surveillance department of the sponsor, however, concluded the event to be unrelated to the basal and bolus insulins.

AE, adverse event; IDet, insulin detemir; NPH, neutral protamine Hagedorn.

Supplementary Table IV. Common adverse events (occurring in ≥4 offspring in any treatment group) by system organ class vigilance.

	IDet			NPH		
	n	**%**	**Episodes/ child**	***n***	**%**	**Episodes /child**
Events	56	36.8	2.2	55	34.8	2.7
Pregnancy, puerperium, and perinatal conditions	26	17.1	1.3	27	17.1	1.3
Respiratory, thoracic and mediastinal disorders	13	8.6	1.1	11	7.0	1.4
Nervous system disorders	5	3.3	1.0	9	5.7	1.8
Investigations	3	2.0	1.0	7	4.4	1.0
Hepatobiliary disorders	5	3.3	1.0	3	1.9	1.0

IDet, insulin detemir; NPH, neutral protamine Hagedorn.

Supplement S5. Detail of trial sites.

4 trial sites in Buenos Aires, Argentina; Cordoba, Argentina; 3 trial sites in Vienna, Austria; Broadmeadow, New South Wales, Australia; Elizabeth Vale, South Australia, Australia; St Leonards, New South Wales, Australia; Camperdown, New South Wales, Australia; Garran, Australian Capital Territory, Australia; Sao Paulo, São Paulo, Brazil; Porto Alegre, Rio Grande do Sul, Brazil; Curitiba, Paraná, Brazil; 2 trial sites in Toronto, Ontario, Canada; London, Ontario, Canada; Montreal, Quebec, Canada; Calgary, Alberta, Canada; Edmonton, Alberta, Canada; Vancouver, British Columbia, Canada; Québec, Quebec, Canada; Winnipeg, Manitoba, Canada; Cambridge, Ontario, Canada; Copenhagen, Denmark; Aarhus, Denmark; Aalborg, Denmark; Alicante, Spain; Santander; Spain; Sevilla, Spain; Barcelona, Spain; Madrid, Spain; Helsinki, Finland; Lille, Nord-Pas-de-Calais, France; Angers, Pays de la Loire, France; Nimes, Languedoc-Roussillon, France; Toulouse, Midi-Pyrénées, France; Bondy, Île-de-France, France; Montpellier, Languedoc-Roussillon, France; Strasbourg, Alsace, France; Valenciennes, Nord-Pas-de-Calais, France; Zagreb, Croatia; 2 trial sites in Dublin, Republic of Ireland; Petah Tikva, Israel; Bergen, Norway; Trondheim, Norway; Tønsberg, Norway; Lodz, Poland; Zabrze, Poland; Krakow, Poland; Lublin, Poland; Olsztyn, Poland; Wroclaw, Poland; Szczecin, Poland; 2 trial sites in Warszawa, Poland; 3 trial sites in Moscow, Russia; Saint Petersburg, Russia; Novosibirsk, Russia; Tumen, Russia; Durban, South Africa; Bristol, UK; Middlesborough, UK; Northampton, UK; Blackburn; UK; Southampton, UK; Waford, UK; Belfast, UK; Exeter, UK; Plymouth, UK; Leicester, UK; London, UK; Birmingham, UK; Norwich, UK.