

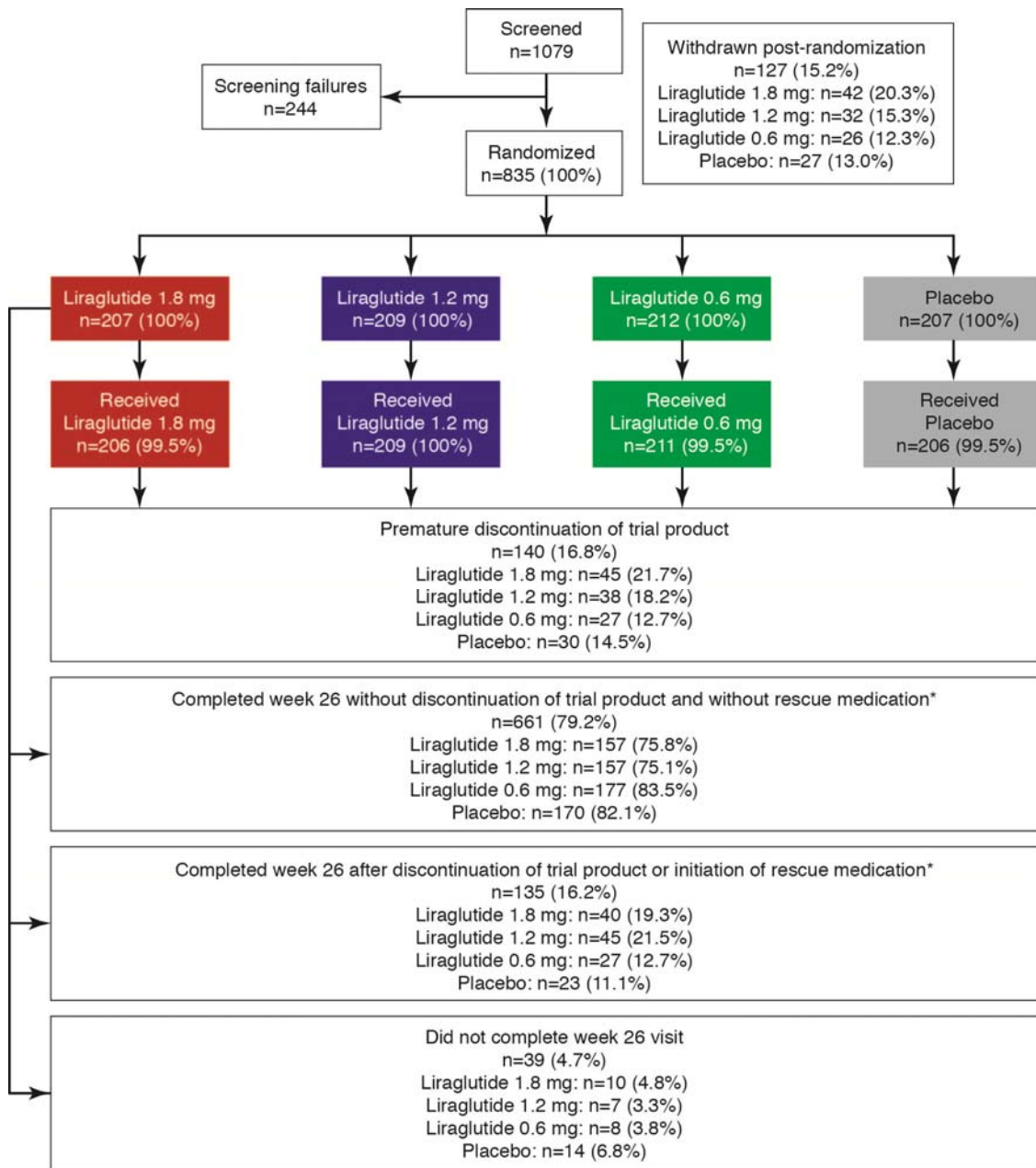
SUPPLEMENTARY DATA

Supplementary Figure S1. Subject disposition.

*The criterion for deterioration in glycemic control was defined as 3 consecutive days pre-breakfast SMPG >15.0 mmol/L (270 mg/dL) starting at Week 6, on the capped insulin dose unless intercurrent illnesses were the cause. In case of deterioration of the glycemic control before Week 6 and considered by the investigator to be a safety issue, the investigator was free to decide that the criterion for rescue treatment was met. During the trial, if the criterion for rescue treatment was met, subjects were to continue on the randomized liraglutide or placebo treatment and were allowed to intensify their insulin dose above the insulin dose cap according to need. Subjects were to continue in the trial and generate efficacy and safety data. Percentages are based on randomized subjects. The trial was initiated 08 May 2014, total trial duration was 32 weeks and consisted of a 2 week screening period, a dose initiation and escalation period of 2-4 weeks a maintenance period of 22-26 weeks (dependent on dose/dose escalation scheme) and a 4-week follow-up period. The trial was completed 27 April 2015.

n, number of subjects; SMPG, self-monitoring of plasma glucose

SUPPLEMENTARY DATA



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Supplementary Table S1. Demographics and baseline characteristics of subjects with baseline fasting C-peptide \geq LLOQ.

	Liraglutide 1.8 mg (n=33)	Liraglutide 1.2 mg (n=33)	Liraglutide 0.6 mg (n=36)	Placebo (n=23)
Age (years)*	44.6 [22;68]	39.8 [21;64]	46.4 [19;57]	44.9 [19;68]
Female : male (%)	58;42	41;59	50;50	48;52
Duration of type 1 diabetes [years]*	10.7 [1;43]	13.6 [3;40]	14.0 [1;54]	10.8 [1;34]
Total insulin dose (U/day) (geometric mean)				
MDI	55 (n=27)	50 (n=26)	62 (n=31)	58 (n=19)
CSII	66 (n=5)	41 (n=7)	48 (n=5)	56 (n=4)
Hypoglycemic unawareness (yes/no) (%)	0/100	6/94	3/97	4/96
Severe hypoglycemia within last year (0/>1) (%)	97/3	88/12	100/0	91/9
Body weight (kg)	83.6	87.4	85.5	85.0
BMI (kg/m ²)	29.1	29.6	29.3	29.0
HbA _{1c} (%)	8.22	8.19	8.08	8.32
HbA _{1c} (mmol/mol)	66.3	66.0	64.8	67.4
Fasting C-peptide (nmol/L)	0.11	0.08	0.12	0.11

*[Min;Max].

BMI, body mass index; CSII, continuous subcutaneous insulin infusion; HbA_{1c}, glycated hemoglobin; LLOQ, lower limit of quantification (0.03 nmol/L); MDI, multiple daily injections

SUPPLEMENTARY DATA

Supplementary Table S2. Additional safety endpoints – on treatment summary.

	Liraglutide 1.8 mg (n=206)				Liraglutide 1.2 mg (n=209)				Liraglutide 0.6 mg (n=211)				Placebo (n=206)	
	W0	W26	ETR/ETD*	p-value	W0	W26	ETR/ETD*	p-value	W0	W26	ETR/ETD*	p-value	W0	W26
Lipase [†] (U/L)	24.99	36.35	1.56	<0.0001	26.95	35.13	1.51	<0.0001	25.00	33.80	1.45	<0.0001	23.69	23.34
Amylase [‡] (U/L)	55.74	56.63	1.10	<0.0001	54.23	56.32	1.10	0.0002	54.91	55.90	1.09	0.0005	54.37	51.40
Calcitonin (ng/L) [§]														
Median	1.00**	1.00	-	-	1.00**	1.00	-	-	1.00**	1.00	-	-	1.00**	1.00
Min;max	1.0;22.7	1.0;18.6	-	-	1.0;25.2	1.0;12.9	-	-	1.0;19.2	1.0;16.3	-	-	1.0;14.3	1.0;17.7
<LLOQ (%)	62.1	69.8	-	-	62.7	66.7	-	-	61.1	64.6	-	-	65.0	66.3
≥LLOQ (%)	37.9	30.2	-	-	37.3	33.3	-	-	38.9	35.4	-	-	35.0	33.7
Pulse (bpm)	74.17	79.31	3.52*	0.0002	72.46	78.00	2.21*	0.0163	73.44	78.06	2.27*	0.0124	73.70	75.79
SBP (mm/Hg)	125.05	121.48	-4.74*	0.0002	125.68	122.00	-4.23*	0.0007	124.86	123.81	-2.41*	0.0500	124.17	126.23
DBP (mm/Hg)	75.73	75.28	-1.20*	0.1377	75.04	75.46	-1.02*	0.2009	76.90	75.36	-1.13*	0.1531	75.95	76.49

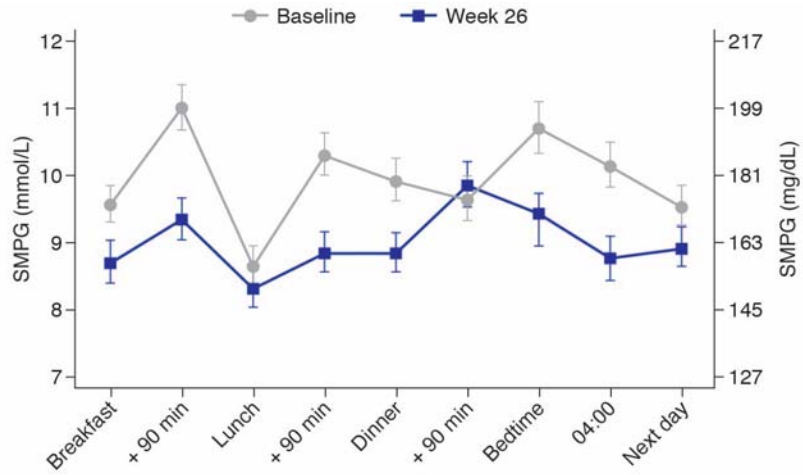
ETR/ETD is compared with placebo. *ETD; **Week -2; [†]lipase normal range, 16.0 to 63.0 U/L; [‡]amylase normal range, 28.0 to 100.0 U/L; [§]calcitonin normal range, 0.0 to 5.0 ng/L (women) and 0.0 to 8.4 ng/L (men).

DBP, diastolic blood pressure; ETR, estimated treatment ratio; ETD, estimated treatment difference; LLOQ, lower limit of quantification; n, number of subjects; SBP, systolic blood pressure; W; week

SUPPLEMENTARY DATA

Supplementary Figure S2. 9-point self-measured plasma glucose profile for the liraglutide 1.8 mg group at Week 0 (baseline) and Week 26.

SMPG, self-monitoring of plasma glucose



SUPPLEMENTARY DATA

Narrative for subject with C-cell hyperplasia

A 60-year-old female had no previous thyroid condition and no suggestive signs or symptoms of thyroid disease. No thyroid ultrasound had been performed previously.

At screening visit 12 days prior to randomization, the patient had a slightly elevated value of calcitonin 22.9 ng/L (normal range 0-5 ng/L). This led to further investigations as the protocol recommended further action and investigations by the investigator for calcitonin values above 20 ng/L.

Day 0, randomized to liraglutide 1.8 mg daily and took study drug for approximately 3 weeks.

Day 24, neck ultrasound demonstrated a 22 mm nodule in the right thyroid lobe. Medullary thyroid carcinoma was suspected. Radioiodine uptake/thyroid scanning was not performed.

Day 28, repeat calcitonin level was 16.9 ng/L at a local laboratory.

Day 31, the patient underwent a fine needle aspiration showing colloidal-cystic nodule. Calcitonin in the aspirate was elevated to 438 pg/ml.

Day 38, the patient was withdrawn from study related to elevated calcitonin.

Day 51, the patient was admitted to the hospital and a neck computed tomography (CT) was performed, which confirmed a hypodense nodule.

Day 206, a genetic evaluation was performed (result not available).

Day 232, the patient was admitted again to have a thyroidectomy performed.

Day 233, the patient had a thyroidectomy performed. Histologic examination revealed macrofollicular plurinodular hyperplasia of the thyroid and C-cell hyperplasia.

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Albany Medical College	Susan Flaherty	Albany
West Broadway Clinic	Isam Marar	Council Bluffs

SUPPLEMENTARY DATA

West Broadway Clinic	Diana Rabadi-Marar	Council Bluffs
Mercury Street Medical Group	John Pullman	Butte
Mercury Street Medical Group	Kim Merritt	Butte
Mercury Street Medical Group	Erin Williams-Leber	Butte
Diablo Clinical Research, Inc.	Mark Christiansen	Walnut Creek
Diablo Clinical Research, Inc.	Leonard Chuck	Walnut Creek
Diablo Clinical Research, Inc.	Helen Stacey	Walnut Creek
Diablo Clinical Research, Inc.	Richard Weinstein	Walnut Creek
Radiant Research Inc. – Murray	Michael Adams	Murray
Radiant Research Inc. – Murray	Janeth Castaneda	Murray
Radiant Research Inc. – Murray	Janna Espinosa-Thomas	Murray
Radiant Research Inc. – Murray	JeNeil Ingram	Murray
Radiant Research Inc. – Murray	Mark Johnston	Murray
Radiant Research Inc. – Murray	Rachel Law	Murray
AMCR Institute Inc	Timothy Bailey	Escondido
AMCR Institute Inc	Yvonne Bedolla	Escondido
AMCR Institute Inc	Kristi Cobb	Escondido
AMCR Institute Inc	Trent Davis	Escondido
AMCR Institute Inc	Francisca Fernandez	Escondido
AMCR Institute Inc	Carmen Franco-Cline	Escondido
AMCR Institute Inc	Brandee Ibarra	Escondido
AMCR Institute Inc	Roya Jannesari	Escondido
AMCR Institute Inc	Angela Owens	Escondido
Larry Stonesifer	Larry Stonesifer	Federal Way
Larry Stonesifer	Heather Baldwin	Federal Way
Larry Stonesifer	Marcia Miller	Federal Way
Advanced Research Institute	Jack Wahlen	Ogden
Advanced Research Institute	Shannah Aleiwe	Ogden
Advanced Research Institute	Mark Hansen	Ogden
Advanced Research Institute	Spencer Hibbert	Ogden
Advanced Research Institute	Jessica Jex	Ogden
Advanced Research Institute	Jeffrey Olsen	Ogden
Advanced Research Institute	Hilary Wahlen	Ogden

SUPPLEMENTARY DATA

Advanced Research Institute	Jonathan Winkfield	Ogden
Advanced Research Institute	Bryce Woolsey	Ogden
Rainier Clinical Research Center Inc	Allen Sussman	Renton
Rainier Clinical Research Center Inc	Ronald Brazg	Renton
Rainier Clinical Research Center Inc	Carole Burton	Renton
Rainier Clinical Research Center Inc	Aimee Jones	Renton
Rainier Clinical Research Center Inc	Leslie Klaff	Renton
Rainier Clinical Research Center Inc	Joanne Nelner	Renton
Rainier Clinical Research Center Inc	Stephanie Wagoner	Renton
Northwestern University	Grazia Aleppo	Chicago
Northwestern University	Mark Molitch	Chicago
Atlanta Diabetes Associates	Bruce Bode	Atlanta
Atlanta Diabetes Associates	Jennifer Boyd	Atlanta
Atlanta Diabetes Associates	Joseph Johnson	Atlanta
Christie Clinic, LLC	John Stokes	Champaign
Christie Clinic, LLC	Kathleen Collins	Champaign
Christie Clinic, LLC	Tonya Peidl	Champaign
Christie Clinic, LLC	Patti Smith	Champaign
North Shore University Health System	Liana Billings	Skokie
North Shore University Health System	Herman Blomeier	Skokie
North Shore University Health System	Alexandra Reiher	Skokie
North Shore University Health System	Asantewaa Ture	Skokie
North Shore University Health System	Janet Yoo	Skokie
Diabetes & Endocrino	Peter Bressler	Dallas
Diabetes & Endocrino	Julia Dilliard	Dallas
Diabetes & Endocrino	Daryl Flanders	Dallas

SUPPLEMENTARY DATA

Diabetes & Endocrino	Michelle Katz	Dallas
Diabetes & Endocrino	Jonathan Leffert	Dallas
Diabetes & Endocrino	Alexandra Ramirez	Dallas
Diabetes & Endocrino	Susan Watkins	Dallas
University of Washington	Irl Hirsch	Seattle
University of Washington	Christina Peterson	Seattle
University of Washington	Barbara Ricker	Seattle
University of Washington	Pamela Thomson	Seattle
University of Washington	Dace Trence	Seattle
University of Washington	Subbulaxmi Trikudanathan	Seattle
University of Washington	Tracy Tylee	Seattle
University of Washington	Lorena Wright	Seattle
Barbara Davis Center For Childhood Diabetes	Paul Wadwa	Aurora
Barbara Davis Center For Childhood Diabetes	Guy Alonso	Aurora
Barbara Davis Center For Childhood Diabetes	Dena Gottesman	Aurora
Barbara Davis Center For Childhood Diabetes	Nhung Nguyen	Aurora
Barbara Davis Center For Childhood Diabetes	Viral Shah	Aurora
Barbara Davis Center For Childhood Diabetes	Robert Slover	Aurora
Queens Hospital Center	Isaac Sachmechi	Jamaica
Queens Hospital Center	Paul Kim	Jamaica
Queens Hospital Center	David Reich	Jamaica
Amarillo Medical Specialists	William Biggs	Amarillo
Amarillo Medical Specialists	Kenny Brantley	Amarillo
Amarillo Medical Specialists	Leonard Dodson	Amarillo
Amarillo Medical Specialists	Stephen Usala	Amarillo
New West	Kenneth Cohen	Golden

SUPPLEMENTARY DATA

Physicians		
New West Physicians	Amber Bretz	Golden
New West Physicians	Bristol Pavol	Golden
Medical Investigations Inc.	James Thrasher	Little Rock
Medical Investigations Inc.	Teresa Nimmo	Little Rock
Medical Investigations Inc.	Amanda Stubbs	Little Rock
Medical Investigations Inc.	Lesa Thrasher	Little Rock
Billings Clinical Research Center	Christopher Sorli	Billings
Billings Clinical Research Center	Reed Christensen	Billings
Billings Clinical Research Center	Lindsey McDonnell	Billings
Precision Trials, LLC	Richard Kelly	Phoenix
Precision Trials, LLC	Michael Drury	Phoenix
Precision Trials, LLC	Peter Young	Phoenix
David M. Gorson, MD	David Gorson	Bennington
David M. Gorson, MD	Kristen McCart	Bennington
Research Management, Inc	Paul Moore	Austin
Research Management, Inc	Kavita Juneja	Austin
Research Management, Inc	Linda Cook	Austin
Research Management, Inc	Jackie Decker	Austin
Research Management, Inc	Deanna Hamilton	Austin
Research Management, Inc	Rachel Malish	Austin
Research Management, Inc	Paul Moore	Austin
Central FL Endocrin & Diabetes	Carlos Pacheco	Maitland
Central FL Endocrin & Diabetes	Kelly Cook	Maitland
Central FL Endocrin & Diabetes	Penny Glickman	Maitland
Central FL Endocrin & Diabetes	Charlene Klinger	Maitland
John Muir Physician Network	Anna Chang	Concord

SUPPLEMENTARY DATA

Clinical		
John Muir Physician Network Clinical	Carolyn Paulson	Concord
John Muir Physician Network Clinical	Sophia Stalters	Concord
John Muir Physician Network Clinical	Douglas Zlock	Concord
Sestron Clinical Research	Barbara Biggs	Marietta
Sestron Clinical Research	Glenn Gatipon	Marietta
Sestron Clinical Research	Amy Herzog	Marietta
Sestron Clinical Research	Linda Sweeney	Marietta
Sestron Clinical Research	Sestilia Tirillo	Marietta
PMG Research of Wilmington, LLC	Kevin Cannon	Wilmington
PMG Research of Wilmington, LLC	Lee Ann McGinnis	Wilmington
PMG Research of Wilmington, LLC	John Parker	Wilmington
Lillestol Research LLC	Michael Lillestol	Fargo
Lillestol Research LLC	Jamie Brown	Fargo
Kentucky Diabetes-Endocrinology Center	Lyle Myers	Lexington
Kentucky Diabetes-Endocrinology Center	Diane Ballard	Lexington
Kentucky Diabetes-Endocrinology Center	Wendall Miers	Lexington
Kentucky Diabetes-Endocrinology Center	Rachel Sparks	Lexington
Valley Research	Paul Norwood	Fresno
Valley Research	Lucas Anderson	Fresno
Valley Research	Chelsea Flowe	Fresno
Coastal Metabolic Research Center	Ronald Chochinov	Ventura
Coastal Metabolic Research Center	Graciela Hernandez	Ventura
Palm Research Center Inc.	Samer Nakhle	Las Vegas
Palm Research Center Inc.	Rachel Bowers	Las Vegas
Palm Research Center Inc.	Serena Klugh	Las Vegas
Palm Research	Betsy Palal	Las Vegas

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Center Inc.		
Palm Research Center Inc.	Amy Soto	Las Vegas