Diabetes Studies

RADIANT

Rare and Atypical Diabetes Network

Study Goal(s):
The Rare and Atypical DIAbetes NeTwork (RADIANT) is dedicated to characterizing (discovering and defining) rare and atypical forms of diabetes.

Eligibility Criteria:
Individuals with atypical diabetes across the lifespan

Need healthy volunteers: No

Open to Enrollment: Yes

Investigators: Maria J. Redondo, MD, PhD, MPH (Site Principal Investigator), Mustafa Tosur, MD (Co-investigator), Stephanie Sisley, MD (Co-investigator), Marcela Astudillo, MD (Co-investigator)

Supported by: National Institutes of Health, U54 Award

Contact: Adriana Cardenas (Study Coordinator): adriana.cardenas@bcm.edu; Maria J Redondo, MD, PhD (Site Principal Investigator): redondo@bcm.edu

Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY and TODAY2)

Study Goal(s):
To understand the best treatment options for youth with type 2 diabetes and the complications related to early onset type 2 diabetes.

Eligibility Criteria: 12 to 18 year-old children and adolescents; normal weight and overweight with and without type 2 diabetes.

Need healthy volunteers: no

Open to Enrollment: no

Investigators: Siripoom Mckay, MD (Site Principal Investigator), Fida Bacha, MD (Co-Investigator); Morey Haymond, MD (Co-Investigator), Sheila Gunn (Co-Investigator)

Supported by: National Institutes of Health

Contact: Siripoom McKay, MD (Principal Investigator)

TrialNet Affiliate Site: Pathway to Prevention

Study Goal(s):
To identify individuals at risk for type 1 diabetes

Eligibility Criteria:
Relatives of individuals with type 1 diabetes

Need healthy volunteers: No

Open to Enrollment: Yes

Investigators: Maria J. Redondo MD, PhD (Principal Investigator), Mustafa Tosur, MD (Co-investigator)

Supported by: National Institutes of Health

Contact: Maria J. Redondo, MD, PhD (Principal Investigator): redondo@bcm.edu; Adriana Cardenas (Study Coordinator): adriana.cardenas@bcm.edu

https://www.trialnet.org/participate

TrialNet Affiliate Site: Prevention and New Onset Trials

Study Goal(s):
Conduct clinical trials for prevention of type 1 diabetes and in new onset type 1 diabetes

Eligibility Criteria:
Follow-up of participants in TN18

Need healthy volunteers: No

Open to Enrollment: No

Investigators: Maria J. Redondo, MD, PhD, MPH (Site Principal Investigator), Mustafa Tosur, MD (Co-investigator), Daniel DeSalvo, MD (Co-investigator)

Supported by: National Institutes of Health

Contact: Maria J. Redondo MD, PhD (Site Principal Investigator): redondo@bcm.edu, Adriana Cardenas (Study Coordinator): adriana.cardenas@bcm.edu

https://www.trialnet.org/participate

T1D Exchange Quality Improvement Collaborative (QIC)

Study Goal(s):
The T1D Exchange QIC brings together more than 20 clinics, situated across the US that treat over 40,000 individuals with type 1 diabetes. The Collaborative relies on an embedded and systemic approach: individual providers are empowered to identify areas of unmet need within their clinic, make small changes in care that scale up through the Collaborative to create best practices, which are then shared among and implemented by members at other clinics.

Eligibility Criteria: None

Need healthy volunteers: No

Open to Enrollment: No

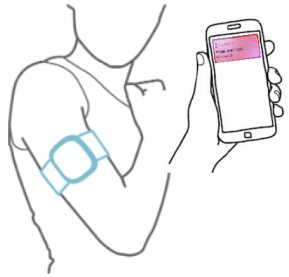
Investigator: Daniel DeSalvo, MD (Site Principal Investigator), Sarah Lyons, MD (Co-investigator), Rona Sonabend, MD (Co-investigator), Selorm Dei-Tutu, MD (Co-investigator)

Supported by: Helmsley Charitable Trust

Contact: Daniel DeSalvo, MD (Site PI): Daniel.DeSalvo@bcm.edu

https://t1dexchange.org/quality-improvement/quality-improvement

SenSE: Multimodal Noninvasive Wearable Sensors and Machine Learning for Predicting Critical Glycemic Events



Study Goal(s):
This project seeks to develop a multimodal wearable sensing platform and machine learning algorithms that can predict glycemic events non-invasively.

Eligibility Criteria: None

Need healthy volunteers: No

Open to Enrollment: No

Investigators: Siripoom McKay, MD (Site Principal Investigator), Daniel DeSalvo, MD (Co-PI)

Supported by: National Science Foundation

Contact: Siripoom McKay, MD (Site PI): siripoom@bcm.edu, Daniel DeSalvo, MD (Co-PI): Daniel.DeSalvo@bcm.edu, Carolina Villegas (Study Coordinator): Carolina.Villegas@bcm.edu

https://www.nsf.gov/awardsearch/showAward?AWD_ID=2037383&HistoricalAwards=false

SWPDC FDA Real World Evidence Study

Study Goal(s):
The goal of the type 1 diabetes (T1D) real world evidence (RWE) demonstration project is to develop a standalone software system and application that will provide contextual and clinically relevant data dashboards synthesized from multiple devices to enable improved patient encounters and clinical management of acute glycemic events and impact long term clinical outcomes for youth with T1D.

Eligibility Criteria: None

Need healthy volunteers: No

Open to Enrollment: Yes

Investigators: Daniel DeSalvo, MD (Site Principal Investigator), Siripoom McKay, MD (Co-investigator), Sruthi Menon, MD (Co-investigator), Marisa Hilliard, PhD (Co-investigator)

Supported by: U.S. Food and Drug Administration

Contact: Daniel DeSalvo, MD (Site Principal Investigator): Daniel.DeSalvo@bcm.edu, Carolina Villegas (Study Coordinator): Carolina.Villegas@bcm.edu

http://swpdc.org/rwe-project

Type 1 Diabetes Genetic Risk Scores (GRS) in TrialNet

Study Goal(s):
To test the type 1 diabetes genetic risk scores for predication of type 1 diabetes and selection of candidates for prevention trials

Eligibility Criteria:
TrialNet participants

Need healthy volunteers: No

Open to Enrollment: No

Investigators: Maria J. Redondo, MD, PhD (Principal Investigator), Mustafa Tosur, MD (Co-investigator)

Supported by: National Institutes of Health, R01 Award

Contact: Maria J. Redondo, MD, PhD (Principal Investigator): redondo@bcm.edu

Race/ethnicity-specific Type 1 Diabetes Genetic Risk Score in Pediatric Diabetes

Study Goal(s):
To test type 1 diabetes genetic risk scores in combination with other characteristics present at diabetes diagnosis to accurately and timely classify diabetes type in racially/ethnically diverse youth.

Eligibility Criteria:
Youth with diabetes

Need healthy volunteers: No

Open to Enrollment: Not yet

Investigators: Maria J. Redondo MD, PhD (Principal Investigator), Mustafa Tosur MD (Co-investigator)

Supported by: National Institutes of Health, R01 Award

Contact: Maria J. Redondo MD, PhD (Principal Investigator): redondo@bcm.edu

Omnipod Horizon Pivotal Study

Study Goal(s):
This study is a single-arm, multi-center, prospective clinical study to evaluate the effectiveness of the Omnipod Horizon Automated Glucose Control System in children aged 6-13.9 years and adults aged 14-70 years.

Eligibility Criteria: None

Need healthy volunteers: No

Open to Enrollment: No

Investigators: Daniel DeSalvo, MD (Site Principal Investigator), Siripoom McKay, MD (Co-investigator)

Supported by: Insulet

Contact: Daniel DeSalvo, MD (Site Principal Investigator): Daniel.DeSalvo@bcm.edu, Carolina Villegas (Study Coordinator): Carolina.Villegas@bcm.edu

https://clinicaltrials.gov/ct2/show/NCT04196140

Omnipod Horizon Preschool Cohort

Study Goal(s):
This study is a single-arm, multi-center, prospective clinical study to evaluate the safety and effectiveness of the Omnipod Horizon Automated Glucose Control System in preschool children (2-5.9 years) with type 1 diabetes.

Eligibility Criteria: None

Need healthy volunteers: No

Open to Enrollment: No

Investigators: Daniel DeSalvo, MD (Site Principal Investigator), Siripoom McKay, MD (Co-investigator)

Supported by: Insulet

Contact: Daniel DeSalvo, MD (Site Principal Investigator): Daniel.DeSalvo@bcm.edu, Carolina Villegas (Study Coordinator): Carolina.Villegas@bcm.edu

https://clinicaltrials.gov/ct2/show/NCT04476472

Enhancement of Biomarkers for Type 1 Diabetes

Study Goal(s):
To utilize immunologic biomarkers, in particular a variant-specific IA-2 autoantibodies, for type 1 diabetes prediction

Eligibility Criteria:
Individuals with type 1 diabetes

Need healthy volunteers: No

Open to Enrollment: No

Investigators: Massimo Pietropaolo, MD (Principal Investigator), Maria J. Redondo MD, PhD (Co-investigator)

Supported by: National institutes of Health, R01 Award

Contact: Maria J. Redondo, MD, PhD (Co-investigator): redondo@bcm.edu

Endothelial Dysfunction in Youth with Obesity and Type 2 Diabetes

Study Goal(s):
To understand the risk factors and determinants of early vascular dysfunction in youth that may predispose to heart disease in adulthood.

Eligibility Criteria: 12 to 18 year-old children and adolescents; normal weight and overweight with and without type 2 diabetes.

Need healthy volunteers: yes

Open to Enrollment: yes

Investigators: Fida Bacha, MD (Principal Investigator)

Supported by: United States Department of Agriculture/Agricultural Research Service (USDA/ARS)

Contact: Fida Bacha, MD (Principal Investigator); Janette Rodela, RN (Research Nurse)
Janette.Rodela@bcm.edu

Bone Health and Metabolism in Youth

Study Goal(s):
1) To understand how childhood exposures (diet, exercise, and glucose metabolism) may affect bone health in growing children.
2) To investigate how bone hormones may affect glucose metabolism and vascular health in youth.

Eligibility Criteria: 12 to 18 year-old children and adolescents; normal weight and overweight with and without type 2 diabetes.

Need healthy volunteers: yes

Open to Enrollment: yes

Investigators: Fida Bacha, MD (Principal Investigator); Reem Shawar, MD (Co-investigator);

Supported by: United States Department of Agriculture/Agricultural Research Service (USDA/ARS)

Contact: Fida Bacha, MD (Principal Investigator); Janette Rodela, RN (Research Nurse)
Janette.Rodela@bcm.edu

AB Classification Study in Pediatric Diabetes

Study Goal(s):

(1) To test the usefulness of new classification system in pediatric diabetes using islet autoimmunity and insulin production capacity.

(2) To identify biomolecular differences by fasting plasma metabolomics between type 1 diabetes and type 2 diabetes compared to healthy controls.

Eligibility Criteria:

1) 2-17 year old children with new-onset diabetes, diagnosed within last 12 weeks;
2) 15-17 year old children with type 1 and type 2 diabetes, with diabetes duration between 6 months to 10 years

Need healthy volunteers: Yes –(15-17 year old healthy controls)

Open to Enrollment: Yes

Investigators: Mustafa Tosur, MD (Principal Investigator), Maria J. Redondo MD, PhD(Co-Investigator), Serife Uysal MD(Co-Investigator), Marcela Astudillo MD (Co-Investigator)

Supported by: Texas Children's Hospital Pilot Award

Contact: Saima Deen (Study Coordinator): saima.deen@bcm.edu; Mustafa Tosur, MD (Principal investigator): Mustafa.Tosur@bcm.edu

Phase 3 Alogliptin Pediatric Study

Study Goal(s):
To evaluate the efficacy and safety of Alogliptin compared with placebo in adolescents with type 2 diabetes

Eligibility Criteria: 10 to 17 year old children and adolescents with type 2 diabetes

Need healthy volunteers: no

Open to Enrollment: yes

Investigators: Fida Bacha, MD (Site Principal Investigator)

Supported by: Takeda

Contact: Fida Bacha, MD (Site Principal Investigator); Janette Rodela, RN (Research Nurse)
Janette.Rodela@bcm.edu

Phase 3 Exenatide Pediatric Study

Study Goal(s):
To evaluate the efficacy and safety of Exenatide once weekly compared with placebo in adolescents with type 2 diabetes

Eligibility Criteria: Children and adolescents with type 2 diabetes

Need healthy volunteers: no

Open to Enrollment: no

Investigators: Fida Bacha, MD (Site Principal Investigator)

Supported by: Takeda

Contact: Fida Bacha, MD (Site Principal Investigator)

A Phase 3 Randomized Controlled Trial of Ladarixin in New-Onset Type 1 Diabetes

Study Goal(s): This is a phase 3, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of 400 mg twice a day oral ladaraxin in patients with new-onset type 1 diabetes and a low residual β-cell function at baseline.

Eligibility Criteria: 14-20 years old adolescents and young adults with new-onset type 1 diabetes (BCM/TCH Criteria)

Need healthy volunteers: No

Open to Enrollment: Soon

Investigators: Mustafa Tosur, MD (Site Principal Investigator), Maria J. Redondo, MD, PhD (Co-investigator), Serife Uysal, MD (Co-Investigator)

Supported by: Dompe Pharmaceuticals (https://www.dompe.com/en)

Contact: Mustafa Tosur, MD (Site Principal Investigator): mustafa.tosur@bcm.edu

https://clinicaltrials.gov/ct2/show/NCT04628481

DiaBetter Together

Study Goal(s):
This randomized control trial is testing a strengths-based peer support program for young adults with type 1 diabetes who are transitioning from pediatric to adult diabetes healthcare.

Eligibility Criteria:
1) Has a diagnosis of type 1 diabetes of at least 1 year
2) Currently receiving care at a TCH Diabetes Care Center location
3) Between the ages of 17-25 years at enrollment.
4) Exhibits fluency in reading/speaking English.
5) Their endocrine provider confirmed plans to transfer to adult provider in the next 3-6 months.

Need healthy volunteers: No

Open to Enrollment: Soon

Investigators: Marisa Hilliard, PhD (Site Principal Investigator), Sarah Lyons, MD (Co-investigator), Siripoom McKay, MD (Co-investigator), Charles Minard, PhD (Co-investigator), Sridevi Devaraj, MD, PhD (Co-investigator)

Supported by: National Institutes of Health, R01 Award

Contact: Wendy Levy (Project Manager): 832-822-1657

First STEPS

Study Goal(s):
This randomized control trial is testing a stepped care behavioral intervention for parents of young children who are newly diagnosed with type 1 diabetes.

Eligibility Criteria:
1) Child age 1-6 newly diagnosed with type 1 diabetes and parent.
2) Parent age at least 21 years
3) Parent must be able to adequately understand, speak and read English.

Need healthy volunteers: No

Open to Enrollment: No

Investigators: Marisa Hilliard, PhD (Site Principal Investigator), Lefkothea Karaviti, MD (Co-investigator), Katherine Gallagher, PhD (Co-investigator)

Supported by: National Institutes of Health, R01 Award (PI: Streisand, Children's National Hospital)

Contact: Jasmine Jones (Lead Research Coordinator): 832-824-7216

PRISM- Promoting Resilience in Stress Management Intervention

PRISM

Study Goal(s):
This randomized control trial is testing a resilience-building skills program for adolescents with T1D and elevated diabetes distress

Eligibility Criteria:
Adolescents will be eligible if: 1) they are 13-18 years old, 2) diagnosed with T1D >= 12 months, 3) elevated distress score. 4) Speak English fluently (parent can speak Spanish), & 5) Cognitively able to participate in intervention sessions and complete written surveys.

Need healthy volunteers: No

Open to Enrollment: Yes

Investigators: Marisa Hilliard, PhD (Site Principal Investigator), Daniel DeSalvo, MD (Co-investigator)

Supported by: National Institutes of Health, R01 Award (PI: Yi-Fraizer, Seattle Children's Hospital)

Contact: Viena Cao (Lead Research Coordinator): 832-824-3956

Addressing Social Needs and Behavioral Health Early in the Type 1 Diabetes Course to Mitigate Inequitable Health Outcomes among Socioeconomically Disadvantaged Minority Youth

Study Goal(s):
To mitigate health disparities by addressing social needs and behavioral health early in the course of type 1 diabetes.

Eligibility Criteria:
Youth with type 1 diabetes

Need healthy volunteers: No

Open to Enrollment: Not yet

Investigators: Ashley M Butler, PhD (Principal Investigator), Maria J. Redondo, MD, PhD and Dr. Selorm Dei-Tutu, MD (Co-investigators)

Supported by: Baylor College of Medicine

Contact: Ashley M Butler M.D. (Principal Investigator): ambutler@bcm.edu

Endocrine Studies

Setmelanotide Phase 2 Treatment Trial in Patients With Rare Genetic Disorders of Obesity

Study Goal(s): To determine the effect of setmelanotide (RM-493) on weight, hunger assessments and other factors in patients with rare genetic disorders of obesity.

Eligibility Criteria: (at BCM/TCH) ages 6-18 yo with a genetic form of obesity including Smith-Magenis, 16p11.2 deletion syndrome, MC4R, leptin deficiency with loss of response to metreleptin, CPE deficiency, or POMC/PCSK1/LEPR deficiency

Need healthy volunteers: No

Open to Enrollment: Yes

Investigators: Stephanie Sisley, MD (Site Principal Investigator)

Supported by: Rhythm Pharmaceutics (https://www.rhythmtx.com/)

Contact: Stephanie Sisley, MD (Site Principal Investigator): stephanie.sisley@bcm.edu

https://clinicaltrials.gov/ct2/show/NCT03013543

Phase 3 Intranasal Carbetocin in Prader Willi Syndrome

Study Goal(s):
This Phase 3 study is designed to test the effectiveness and tolerability of intranasal carbetocin (LV-101),an oxytocin analog, in participants with Prader-Willi syndrome (PWS).

Eligibility Criteria:
Individuals with atypical diabetes across the lifespan

Need healthy volunteers: No

Open to Enrollment: No

Investigators: Dr. Williams (Site Principal Investigator), Katherine Hwu, MD (Co-investigator)

Supported by: Levo Therapeutics

https://clinicaltrials.gov/ct2/show/NCT03649477 https://www.levotx.com/

Need more info

TEAM - T1D Empowerment and Management and Intervention

Study Goal(s): ??

Eligibility Criteria: ??

Need healthy volunteers: ??

Open to Enrollment: No

Investigators: Ashley M Butler, PhD (Site Principal Investigator), Lefkothea Karaviti, MD (Co-investigator), Marisa Hilliard, PhD (Co-investigator)

Supported by: National Institutes of Health, DP3 Award

Contact: ??