

## Clinical Trials available in Northern California

Study Type	Age	Location/Sponsor	Study name and purpose	Basic inclusion criteria	Commitment/Benefit	Contact/More info.
Prevention	2.5-45	Worldwide, TrialNet	<b>TrialNet:</b> Pathway to Prevention Antibody Screening. Determines risk for developing T1D in family members.	Have a relative with T1D (siblings, cousins, etc. may be at a higher risk)	Blood test at a center or at home (to mail in or take to LabCorp). Determine risk of developing T1D and providing opportunities to join prevention trials if at-risk.	<a href="http://www.trialnet.org">www.trialnet.org</a> or <a href="http://clinicaltrials.gov">clinicaltrials.gov</a>
Prevention	Any	Worldwide, Barbara Davis Center	<b>ASK:</b> Antibody screening for all children. To determine the risk for developing T1D.	Anyone	Blood test at a center or at home (to mail in or take to LabCorp). Determine risk of developing T1D and providing opportunities to join prevention trials if at-risk.	<a href="http://askhealth.org">askhealth.org</a>
Drug/new onset	12-35	Diablo/UCSF	<b>FABULINUS:</b> A study assessing safety and efficacy of frexalimab, a CD40L-antagonist monoclonal antibody, for preservation of pancreatic beta-cell function in adults and adolescents with newly diagnosed type 1 diabetes on insulin therapy.	Diagnosed within 90 days, at least one autoantibody.	1 infusion, wkly. injections for 1 year to help preserve beta cell function.	<b>Diablo Clinical, Walnut Creek:</b> Meaghan Saint (925) 930-7267 ext. 223, <a href="mailto:msaint@diablocinical.com">msaint@diablocinical.com</a> <b>UCSF:</b> Rebecca Wesch 415-476-5984, <a href="mailto:Rebecca.Wesch@ucsf.edu">Rebecca.Wesch@ucsf.edu</a>
Drug/new onset	8-45	Stanford/UCSF	<b>RELAY:</b> The goal of this study is to test rituximab-pvvr and abatacept, one after the other, to learn if using both treatments extend insulin production in newly diagnosed. Recent findings showed that abatacept impacted immune response and preserved insulin production during the one-year treatment period.	Diagnosed within 100 days	All participants will get 4 weekly IV infusions of rituximab-pvvr. Then, after 12 weeks of no treatment, everyone will receive weekly injections (self-administered) of abatacept or placebo for 20 months. Two-thirds of participants will get abatacept; one third will get placebo. Followed by a 2 year follow up	<b>Stanford:</b> Trudy Esrey, <a href="mailto:tesrey@stanford.edu">tesrey@stanford.edu</a> , 650-498-4450, <b>UCSF:</b> Rebecca Wesch 415-476-5984, <a href="mailto:Rebecca.Wesch@ucsf.edu">Rebecca.Wesch@ucsf.edu</a>
Drug/new onset	12-35	Stanford/UCSF	<b>JAKPOT:</b> The goal of this study is to test two different treatments - abrocitinib and ritlectinib – to see if either or both can preserve insulin production in newly diagnosed. Researchers believe these drugs may calm the immune system response that harms beta cells	Diagnosed within 100 days	12 months of treatment plus 12 months of follow up. Oral medication taken daily during treatment phase	<b>Stanford:</b> Trudy Esrey, <a href="mailto:tesrey@stanford.edu">tesrey@stanford.edu</a> , 650-498-4450 <b>UCSF:</b> Rebecca Wesch 415-476-5984, <a href="mailto:Rebecca.Wesch@ucsf.edu">Rebecca.Wesch@ucsf.edu</a>
Drug/new onset	12-28	Stanford	<b>DIAGNODE-3</b> will investigate whether an investigational drug called Diamyd® (rhGAD65) is able to preserve the body's own insulin-producing capacity by halting or delaying the autoimmune attack on the insulin-producing cells (beta cells) in the pancreas.	- Diagnosed within the last 6 months - the HLA haplotype DR3-DQ2 (Stanford will test you for this) - Presence of GAD65 autoantibody (will also be tested for this)	2-month treatment period and be assigned at random. The study drug Diamyd® or placebo (a treatment without the active ingredient), will be given through an injection into a lymph node in the groin during ultrasound imaging by an experienced specialist 3 times during the 2 months	<b>Stanford:</b> Trudy Esrey, <a href="mailto:tesrey@stanford.edu">tesrey@stanford.edu</a> , 650-498-4450
Drug/new onset	18- 60	Diablo Clinical	<b>COVALENT:</b> will investigate whether BMF-215, a menin inhibitor, can preserve insulin production in newly diagnosed. (paused)	-Diagnosed within the last 3 years, or 3 - 15 years -only using insulin for treatment for at least 2 months prior to study -A1C 6.5 to 10	52 week trial, oral medication. There are 3 arms of this trial. Those dx within last 3 years receive 100mg, those dx within 3 - 15 years receive 200 mg, the third arm is the control group.	<b>Note: recruiting in 2025. Diablo Clinical, Walnut Creek:</b> Meaghan Saint (925) 930-7267 ext. 223, <a href="mailto:msaint@diablocinical.com">msaint@diablocinical.com</a> <a href="https://classic.clinicaltrials.gov/ct2/show/NCT06152042">https://classic.clinicaltrials.gov/ct2/show/NCT06152042</a>
Drug	18-60	Diablo Clinical	<b>OPT101:</b> this study is a polymer peptide that reduces inflammation. It has been found to be efficacious in animals both at delaying the onset of diabetes and reversing established diabetes.(will be recruiting second round shortly)	Diagnosed less than 20 years ago.	Infusions over a 30-minute period. At the first and last visits, you will be monitored for the following 8 hours and then for 2 hours on the remainder of this visits which are Days 4, 7, 14 and then weekly for a total of 8 infusions.	<b>Diablo Clinical, Walnut Creek:</b> Meaghan Saint (925) 930-7267 ext. 223, <a href="mailto:msaint@diablocinical.com">msaint@diablocinical.com</a> <a href="https://clinicaltrials.gov/ct2/show/NCT05428943">clinicaltrials.gov/ct2/show/NCT05428943</a>
Drug	18 +	Stanford	<b>FINEONE:</b> evaluating the impact of Finerenone on chronic kidney disease in patients with T1D	T1D and Chronic Kidney Disease (CKD)	6 months of oral study medication and 6 expected visits. Study will provide medication and handle necessary labwork to assess chronic kidney disease, including urine albumin to creatinine ratio (UACR)	<a href="mailto:Ryan.Kingman@stanford.edu">Ryan.Kingman@stanford.edu</a>
Transplant/Cure	>18	UCSF	<b>Transplant:</b> Pancreatic Islets and Parathyroid Gland Co-transplantation for Treatment of Type 1 Diabetes	- Have had liver or kidney transplant and are taking immunosuppression T1D onset < 40 yrs old and insulin dependent for > 5 yrs at enrollment, c-peptide negative	- Co-transplantation of allogeneic parathyroid glands (PTG) with adult pancreatic islets in the intramuscular site to see if patient can become insulin independent.	<b>UCSF:</b> Patricia Brennan, RN, PhD, 415-476-3229, <a href="mailto:Patricia.Brennan@ucsf.edu">Patricia.Brennan@ucsf.edu</a>

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Drug/Cure	18-65	Chicago, Boston, Philadelphia, Miami, other countries	<b>Vertex 264:</b> An islet cell infusion without immunosuppression to provide replacement cells for the islet cells that have been lost or don't work properly in people with diabetes.	T1D > 5 years	1.5 week hospital stay, 90 minute cell infusion, quarterly visits for five years. Half of the visits can be with a home health nurse, half at the clinical trial center. Immunosuppression drugs will be provided. Functional cure.	<a href="https://www.clinicaltrials.gov/ct2/show/NCT05791201">https://www.clinicaltrials.gov/ct2/show/NCT05791201</a>
Insulin/Pump combo.	7-80	Sacramento	<b>780G &amp; FIASP:</b> Evaluation of the MiniMed 780G System in Type 1 Adult and Pediatric Subjects Utilizing Insulin Fiasp	- T1D>2 years for adults, >1 year for children - Not on Metformin, SGLT or GLP-1 drugs at time of screening	120 day study using the Medronic 780G hybrid closed loop system with FIASP insulin	Natalie Marlen, capitolcts@gmail.com, 916-719-7307 or Dr. Prakasam 916-426-1902, prakasg@sutterhealth.org clinicaltrials.gov/study/NCT05224258
Insulin	18-60	Stanford	<b>FIASP: injections into peritoneum (membrane lining the stomach)</b> to advance knowledge of how an implanted pump with ultra-rapid insulin might provide a full closed loop system.	- On insulin pump	3 visits, 2 screening/grouping, 1 to inject ultra-rapid acting insulin into the peritoneum under ultrasound guidance	Ryan Kingman: rkingman@stanford.edu
Device	13-17	UCSF (online)	<b>Extended Bolus Study:</b> Post meal glucose control using an extended bolus for high-fat high protein meals in a closed loop system in patients with Type 1 Diabetes. The purpose of this study is to learn whether an extended bolus will improve blood glucose blood sugar control after foods with high content of fat and protein.	• Have T1D for a year or more • Currently using Control IQ closed loop system • Using an iPhone or Android phone • A1C: 6.0-10.0% • No dietary restrictions or Celiac disease	Study Visits can all take place remotely. There are two short planning visits and then two days of a special breakfast. Participants receive a gift card for up to \$150 for their time and effort.	Study Coordinator: Rebecca Wesch Phone: 415-476-5984 Email: rebecca.wesch@ucsf.edu  Principal Investigator: Dr. Laya Ekhlaspour, MD Phone: 415-514-8531 Email: laya.ekhlaspour@ucsf.edu
Device	14-17	UCSF	<b>FCL@Home:</b> AIDANET fully closed loop insulin pump/CGM system is being tested for 5 days and 4 nights in a hotel/rental house setting with doctors and nurses supervising 24 hr/day. Then the AIDANET system is used at home for another 7 days.	T1D for ≥1 year HbA1c 8.0-12.0% Currently using insulin pump ≥6 months	5 days fully closed loop use in hotel/Airbnb setting, 7 days fully closed loop use at home, 2 week usual care period. \$1,000 stipend.	Study Coordinator: Rebecca Wesch Phone: 415-476-5984 Email: rebecca.wesch@ucsf.edu  Principal Investigator: Dr. Laya Ekhlaspour, MD Phone: 415-514-8531 Email: laya.ekhlaspour@ucsf.edu <a href="https://clinicaltrials.gov/study/NCT06041971">clinicaltrials.gov/study/NCT06041971</a>
Device	2 - 17	Stanford	<b>I3Peds:</b> testing the accuracy and precision of a new 15 day wear continuous glucose monitor by Sinocare	T1D for ≥ 6 months and with a stable insulin regimen for ≥1 month	Age <7: 15 days of wearing 2 study sensors with 1 day of fingerstick accuracy testing. \$760 stipend Age 7+: 15 days of wearing 3 study sensors, with 2-3 days of IV samples for accuracy testing. \$1,200 -\$1,650 stipend	Ryan Kingman: rkingman@stanford.edu
Device	18-80	Stanford	<b>Capillary Biomedical:</b> evaluation of the SteadiSet insulin infusion set with 12 wear periods of up to 7 days each during home use in adults with T1D using Tandem pump with t:slim X2 Control-IQ.	T1D > 1 year; HbA1c < 9.0%; insulin pump use ≥ 1 year; Tandem pump use ≥ 3 months; no use of non-insulin glucose lowering agents (except metformin)	7-day wear period goal for 12 infusion sets; compensation up to \$1,240.	Study coordinator: Bailey Suh Phone: (925) 389-8516 Email: bysuh@stanford.edu  Principal Investigator: Rayhan Lal, MD <a href="https://clinicaltrials.gov/study/NCT06273124">https://clinicaltrials.gov/study/NCT06273124</a>
Device	6-8 years	Stanford	CIP 344: Safety Evaluation of the MiniMed™ 780G System Used in Combination with the DS5 CGM in Children 2-6 Years of Age (SUCCEED2)	Age 2-6 years at time of screening, have a clinical diagnosis of type 1 diabetes for 3 months. Must have a minimum daily insulin requirement of greater than or equal to 6 units on average and an A1C less than 10%.	This study will evaluate the safety of the MiniMed 780G system used in combination with the Disposable Sensor 5 (DS5) CGM in type 1 pediatric subjects (2-6 years of age) in a home setting. The study will consist of 16 visits using different Auto Basal Targets.	Study coordinator: Bailey Suh Phone: (925) 389-8516 Email: bysuh@stanford.edu  Principal Investigator: Rayhan Lal, MD inforay@stanford.edu
Interventional	≥18 years	Stanford, Emory, UVA	<b>AIDING:</b> aims to test the efficacy and safety of AID versus standard of care therapy in the inpatient setting.	Diabetes mellitus diagnosis (except cystic fibrosis- and pregnancy-related); admitted to general (non-ICU) medical-surgical hospital services; requires inpatient insulin therapy	Participants will be randomized to AID + CGM or to MDI + CGM for up to 10 days or until hospital discharge.	Study coordinator: Kailiee Kingston Phone: (734) 855-9538 Email: kailiee@stanford.edu  Principal Investigator: Rayhan Lal, MD <a href="https://clinicaltrials.gov/study/NCT04714216">https://clinicaltrials.gov/study/NCT04714216</a>

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Other	Any	UCSF (online)	<b>Precision Genetics:</b> to learn more about <u>potential gene mutations related to T1D.</u>	1) People with multiple immediate family members with T1D or 2) People with multiple auto-immune disorders (either 2+ or rarer disorders)	Spit in a vial and send it back to the lab. Can do from anywhere. <b>Note:</b> results are not provided but any mutations can be reported back to your Dr. to be followed-up on and retested at another lab.	Michael German: Michael.German@ucsf.edu <a href="https://precisiont1d.uchicago.edu/">https://precisiont1d.uchicago.edu/</a>
Care	12-21	Stanford	<b>BEAD-T1D Trial-</b> The BEAD-T1D study aims to increase the use of diabetes technology among disadvantaged youths. It will explore barriers to care, aiming to improve diabetes management and outcomes in this group. <b>SUCCEED2 Trial-</b> This study is a multi-center, single arm study in insulin-requiring pediatric subjects with type 1 diabetes on the MiniMed 780G system using DS5. The run-in period and study period, together, will be approximately 130 days long.	This trial is for young people aged 12-21 with Type 1 Diabetes, especially from low socioeconomic backgrounds. Participants must be living with a		Ananta Addala - 650-497-9099
Device	2-6	Stanford/UCSF		Must be 2-6 years old and at least on 6 units of insulin	<a href="https://clinicaltrials.stanford.edu/trials/s/NCT06604871.html">https://clinicaltrials.stanford.edu/trials/s/NCT06604871.html</a>	inforay@stanford.edu
Care						