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	**TrialNet:** 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.	www.trialnet.org or clinicaltrials.gov
Prevention	1-17	Worldwide, Barbara Davis Center	**ASK:** Antibody screening for all children. To determine the risk for developing T1D.	All children. May also be available to adults; inquite directly.	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.	askhealth.org
Prevention	0-8	UCSF	**PETITE:** testing safety of Tzield in younger patients	Two autoantibodies and abnormal blood sugars (Stage 2 T1D)	14 day infusion, 20 visits over 26 months.	**UCSF:** Rebecca Wesch 415-476-5984, Rebecca.Wesch@ucsf.edu clinicaltrials.gov
Prevention	12-35	Stanford/UCSF	**STOP:** to see if a low dose of the immunotherapy drug anti-thymocyte globulin (ATG) can delay or prevent T1D	Two autoantibodies and abnormal blood sugars (Stage 2 T1D)	2 day infusion of drug. Overnight hospital stay. Follow-up check-in visits at week 2, then every 3 months.	**Stanford:** Trudy Esrey, tesrey@stanford.edu, 650-498-4450, **UCSF:** Rebecca Wesch 415-476-5984, Rebecca.Wesch@ucsf.edu clinicaltrials.gov
Drug/ new onset	8-45	Stanford/UCSF	**DESIGNATE:** The goal of this study is to see how the study drug, siplizumab, can block or weaken the cells that attack beta cells in the pancreas. This would allow the beta cells to continue to function and produce insulin.	Diagnosed within 1.5 years.	52 week study. Injections at study visits 1x week for the initial 12 weeks, then quarterly.	**Stanford:** Trudy Esrey, tesrey@stanford.edu, 650-498-4450, **UCSF:** Rebecca Wesch 415-476-5984, Rebecca.Wesch@ucsf.edu **NOTE: study paused, being revised**
Drug/new onset	8-45	Stanford/UCSF	**RELAY:** 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	**Stanford:** Trudy Esrey, tesrey@stanford.edu, 650-498-4450, **UCSF:** Rebecca Wesch 415-476-5984, Rebecca.Wesch@ucsf.edu
Drug/new onset	12-35	Stanford/UCSF	**JAKPOT:** The goal of this study is to test two different treatments - abrocitinib and ritlecitinib – 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	**Stanford:** Trudy Esrey, tesrey@stanford.edu, 650-498-4450 **UCSF:** Rebecca Wesch 415-476-5984, Rebecca.Wesch@ucsf.edu
Drug/new onset	12-28	Stanford	**DIAGNODE-3** 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	**Stanford:** Trudy Esrey, tesrey@stanford.edu, 650-498-4450
Drug/new onset	18- 60	Diablo Clinical	**COVALENT:** 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.	**Diablo Clinical, Walnut Creek:** Meaghan Saint (925) 930-7267 ext. 223, msaint@diabloclinical.com https://classic.clinicaltrials.gov/ct2/show/NCT06152042
Drug	18 - 72	Diablo Clinical	Evaluate the effect of a glucagon receptor antagonism by volagidemab (once weekly) on glucose recovery from hypoglycemia after treatment with glucagon	-Diagnosed for at least 2 years -BMI of 18.5 - 35 -using a CGM	Subjects will undergo a baseline Hypoglycemia Recovery Procedure (with glucagon rescue). Subjects will then receive a once weekly shot of volagidemab for 6 weeks. At end of treatment, subjects will undergo a second Hypglycemia Recovery Procedure (with glucagon rescue). Subjects will be followed for additional 6 weeks	**Diablo Clinical, Walnut Creek:** Meaghan Saint (925) 930-7267 ext. 223, msaint@diabloclinical.com https://clinicaltrials.gov/study/NCT06272695

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Drug	18-60	Diablo Clinical	**OPT101:** this study is a polymer peptide that reduces inflamation. 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.	**Diablo Clinical, Walnut Creek:** Meaghan Saint (925) 930-7267 ext. 223, msaint@diabloclinical.com clinicaltrials.gov/ct2/show/NCT05428943
Transplant/ Cure	>18	UCSF	**Transplant:** 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.	**UCSF:** Patricia Brennan, RN, PhD, 415-476-3229, Patricia.Brennan@ucsf.edu
Drug/Cure	18-65	Chicago, Boston, Philadelphia, Miami, other countries	**Vertex 264:** An islet cell infusion without immunospression 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. Immunosupression drugs will be provided. Functional cure.	thttps://www.clinicaltrials.gov/ct2/show/NCT05791201
Insulin/Pump combo.	7-80	Sacramento	**780G & FIASP:** 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 screeening	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	**FIASP:** injections into peritoneum (membrane lining the stomach) 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)	**Extended Bolus Study:** 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	**FCL@Home**: 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 clinicaltrials.gov/study/NCT06041971
Other	Any	UCSF (online)	**Precision Genetics:** to learn more about potential gene mutations related to T1D.	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. **Note:** 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 https://precisiont1d.uchicago.edu/