CLOSED STUDIES FOR DIABETES MELLITUS TYPE 1

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
PREVENTION/REVERSAL													
Safety and Efficacy of INGAP-Peptide in Patients With Type 1 Diabetes	√			Proctor and Gamble	Proctor and Gamble	Both	18 to 65	N/S	Enrollment # not specified	N/S	N/S	Adult	INGAP-Peptide is being tested to attempt to create new beta cells in the pancreas, and to restore the ability to produce insulin in type 1 diabetic patients.
The Diabetes Prevention Trial of Type 1 Diabetes (DPT-1) **(US and Canada)**	√			Skyler, Jay	NIDDK	Both	3 to 45	N/S	Enrollment # not specified	February-94	June-03	Both	To determine whether it is possible to delay or prevent the clinical onset of type 1 diabetes through daily doses of insulin in individuals determined to be at risk for the disease.
PREVENTION OF TREATMENT OF COMPLICATIONS													
Effects of Candesartan Cilexetil (Candesartan) on Diabetic Retinopathy in Type 1 Diabetic Patients Without Retinopathy **(Europe)**			√	AstraZeneca	AstraZeneca	Both	18 to 50	N/S	1,300	August-01	N/S	Adult	The primary objective is to determine whether candesartan, compared to placebo reduces the incidence of diabetic retinopathy in normotensive, normoalbuminuric type 1 diabetic patients without retinopathy.
Renin Angiotensin System Blockage-DN (RASS)**(Canada)**			√	Mauer, Michael	NIDDK	Both	16 to 61	N/S	285	March-97	March-07	Young Adult to Adult	To determine if renin angiotensin medications can prevent or delay the onset of diabetic kidney disease.
Diabetes Control and Complications Trial (DCCT)	√			Crofford, Oscar Cleary, Patricia	NIDDK	Both	13 to 39	N/S	1441	August-83	March-95	Both	To examine whether intensive treatment with the goal of maintaining blood glucose concentrations close to the normal range could decrease the frequency and severity of long-term microvascular and neurologic complications
DIRECT: DIabetic Retinopathy Candesartan Trials. Effects of Candesartan Cilexetil (Candesartan) on Diabetic Retinopathy in Type 1 Diabetic Patients With Retinopathy			√	AstraZeneca	AstraZeneca	Both	18 to 55	N/S	1,850	August-01	N/S	Adult	To determine whether candesartan, compared to placebo reduces the progression of diabetic retinopathy in normotensive, normoalbuminuric type 1 diabetic patients with retinopathy.
LY333531 Treatment for Symptomatic Peripheral Neuropathy in Patients With Diabetes **(International)** (Type 1 and 2)	√			Eli Lilly and Company	Eli Lilly and Company	Both	18+	N/S	200	July-02	December-05	Adult	To determine if an investigational drug is effective in treating nerve malfunction in diabetes. [Some international sites closed June 2006.]
LY333531 Treatment for Symptomatic Peripheral Neuropathy in Patients With Diabetes **(International)** (Type 1 and 2)	√			Eli Lilly and Company	Eli Lilly and Company	Both	18+	N/S	200	July-02	June-06	Adult	To determine if an investigational drug known as LY333531 is effective in treating nerve malfunction in diabetes.
TREATMENT/MANAGEMENT/BEHAVIORAL													
Evaluation of Efficacy and Safety of HMR1964 (Insulin Glulisine) in Subjects With Type 1 Diabetes Mellitus; Insulin Lispro Controlled, Open, Randomized, Parallel Group, Non-Inferiority Study, for 28 Weeks **(Japan)**	√			Koyama, Masayoshi	Sanofi-Aventis	Both	18+	N/S	250	December-04	N/S	Adult	To evaluate non-inferiority in the efficacy of HMR1964 as compared with Insulin lispro in terms of the change in HbA1C from baseline to endpoint. To compare the safety of HMR1964 with insulin lispro.
DirecNet Randomized Clinical Trial to Assess the Effectiveness of the GlucoWatch Biographer in the Management of Type 1 Diabetes in Children	√			Tamborlane, William	NICHD	Both	7 to 17	N/S	200	July-03	November-04	Child	To evaluate the safety and effectiveness of a continuous glucose monitor in children with Type 1 diabetes mellitus (T1DM).
Reimplantation of Subjects With Implantable Insulin Pump Therapy			√	Saudek, Christopher	Hopkins	Both	Age not specified	N/S	Enrollment # not specified	February-03	June-12	N/S	To determine whether subjects previously treated with the implantable insulin pump (IIP) therapy, and now taking insulin by injection, will benefit from re-implantation of IIP.
Comparison of Efficacy and Safety of Insulin Detemir and Insulin Glargine in Patients With Type 1 Diabetes **(Europe and Africa)**	√			Clauson, Per	Novo Nordisk	Both	18+	N/S	366	April-02	N/S	Adult	The aim of the trial is to compare the use of Insulin Detemir twice daily combined with mealtime Insulin Aspart against that of Insulin Glargine once daily combined with mealtime Insulin Aspart. The trial involves patients with Type 1 Diabetes.
The Effect of Insulin Analogues and Human Insulin on the Incidence of Severe Hypoglycaemia in Hypoglycaemia Prone Type 1 Diabetic Patients **(International)**		√		Tarnow, Lise	Steno Diabetes Center	Both	18+	N/S	250	October-06	May-10	Adult	To investigate the effect on the occurrence of severe hypoglycaemia during two different insulin regimens.
A Phase 3B, Multicenter, Open-Label Study Investigating the Clinical Utility and Safety of Pramlintide in Subjects With Type 1 and Type 2 Diabetes Mellitus Who Have Not Achieved Glycemic Targets With Insulin Therapy	√			Porter, Lisa	Amylin Pharmaceuticals	Both	18+	N/S	400	April-03	N/S	Adult	To investigate the clinical utility and safety of pramlintide treatment in subjects with type 1 and type 2 diabetes who are failing to achieve the desired level of glycemic control using insulin therapy.

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Evaluation of the Bioavailability of Pramlintide (Type 1 and 2)	√			Amylin Pharmaceuticals	Amylin Pharmaceuticals	Both	18 to 70	N/S	Enrollment # not specified	June-02	N/S	Adult	To examine the bioavailability of pramlintide in normal weight and overweight subjects with type 1 and type 2 diabetes mellitus using insulin.
Evaluation of Dose-Titration of Pramlintide During Initiation of Therapy in Patients Trying to Improve Glucose Control	√			Amylin Pharmaceuticals	Amylin Pharmaceuticals	Both	18+	N/S	Enrollment # not specified	April-02	N/S	Adult	To investigate the safety of pramlintide treatment using pramlintide dose-titration coupled with insulin adjustments in subjects with type 1 diabetes who are actively trying to improve their glycemic control.
Evaluation of the Effect of Pramlintide on Satiety and Food Intake (Type 1 and 2) **(Australia)**	√			Amylin Pharmaceuticals	Amylin Pharmaceuticals	Male	18 to 70	N/S	Enrollment # not specified	July-02	N/S	Adult	To evaluate the effect of pramlintide on satiety and food intake in normal-weight and obese non-diabetic subjects and in insulin-treated subjects with type 1 and type 2 diabetes.
Safety and Efficacy of Human Insulin Inhalation Powder in Patients With Type 1 Diabetes Mellitus	√			Eli Lilly and Company	Eli Lilly and Company	Both	18+	N/S	Enrollment # not specified	N/S	Ns	Adult	This is research study of a study drug known as LY041001 or human insulin inhalation powder (HIIP). HIIP is a powder form of insulin made to be inhaled through the mouth and into the lungs using a special handheld device.
A Pivotal Long-Term, Open-Label, Parallel Study of the Efficacy and Safety of Human Insulin Inhalation Powder in Patients With Type 1 Diabetes Mellitus			√	Eli Lilly and Company	Eli Lilly and Company	Both	18+	N/S	400	July-05	May-08	Adult	To evaluate the safety and efficacy of the Lilly/Alkermes inhaled insulin system compared to injected pre-meal insulin in non-smoking patients with type 1 diabetes.
2 Year Efficiency and Safety Comparison of Insulin Detemir and NPH Insulin in Type 1 Diabetes **(International)**			√	Clauson, Per	Novo Nordisk	Both	18+	N/S	500	June-04	N/S	Adult	The aim of this research study is to compare the efficacy (reduction in HbA1c and in blood glucose levels) of insulin detemir compared to NPH insulin administered as basal insulin for the treatment of type 1 diabetes and to verify the safety of use (number and severity of episodes of hypoglycemia, body weight, and insulin antibodies and side effects).
Italian Experience Trial for the Implementation of the Use of Lantus in Basal - Bolus Regimen in Type I Diabetes Mellitus Patients **(International)**	√			Georges, Paizis	Sanofi-Aventis (Japan)	Both	18 to 60	N/S	960	November-02	N/S	Adult	To demonstrate that the new regimen (insulin glargine+regular insulin) is no worse than the reference regimen (insulin glargine+lys-pro insulin) in reducing the incidence of severe nocturnal hypoglycemia at the end point; the secondary purpose is to compare the two study regimens as far as the glycemic control (measured by HbA1c), the daily Mean Blood Glucose (MBG) and the mean amplitude of glycemic excursion (MAGE index), calculated on the basis of Self Monitoring Blood Glugose (SMBG) data, are concerned and to verify the safety of basal insulinization with Lantus.
A 52-Week Multicenter, Open-Label, Randomized, Parallel, Two - Arm Study Comparing Exubera (Inhaled Human Insulin) Vs. Humalog (Insulin Lispro), Both In Combination With Insulin Glargine In Subjects With Type 1 Diabetes Mellitus		√		Pfizer	Pfizer	Both	18+	N/S	340	November-06	N/S	Adult	To compare efficacy and safety of Exubera vs Humalog in patients with type 1 diabetes mellitus.
AT.LANTUS Main Study: A Phase IIIb/IV, Multinational, Multicentre, Randomised, Open Study to Establish the Optimal Method for Initiating and Maintaining Lantus® (Insulin Glargine) Therapy Based on a Comparison of Two Treatment Algorithms to Determine Optimal Metabolic Outcomes, Safety, and Satisfaction in Subjects With Type 1 Diabetes Mellitus/ "HALT" Sub-Study: Multicentre, Open Clinical Trial to Assess the Effect of Insulin Glargine on Symptomatic Hypoglycaemia, Fear of Hypoglycaemia and Quality of Life in Patients With Type 1 Diabetes	√			Sinnassamy, Patrick	Sanofi-Aventis	Both	18+	N/S	2,346	April-02	N/S	Adult	Main Study: To determine the optimal treatment algorithm for insulin glargine based on the incidence of severe hypoglycaemia. Substudy: To test the hypothesis that titration regimens involving insulin glargine are associated with changes in the rate of symptomatic hypoglycaemic episodes together with changes in Fear of Hypoglycaemia as measured by the HFS-98 Questionnaire in Type I diabetes.(**Target Number of patients for the Sub-study: 250)
Insulin Aspart vs. Insulin Lispro vs. Regular Insulin in Pediatric Population	√			Hale, Paula	Novo Nordisk	Both	6 to 18	N/S	300	June-02	November-03	Child	Not specified - Insulin Aspart vs. Insulin Lispro vs. Regular Insulin in Pediatric Population.

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Efficacy and Safety of Insulin Glulisine Compared With Insulin Lispro in Children and Adolescents With Type 1 Diabetes Mellitus: A 26 Week, Multicenter, Open, Parallel Clinical Trial			√	Philotheou, Arethi	Sanofi-Aventis	Both	4 to 17	N/S	560	March-05	March-07	Child	The purpose of this study is to determine if insulin glulisine (Apidra) is as safe and effective a rapid acting insulin as insulin lispro (Humalog) in children and adolescents with type 1 diabetes mellitus
Efficacy and Safety Comparison of Insulin Detemir Plus Insulin Aspart Versus Insulin Glargine Plus Insulin Aspart in Type 1 Diabetes **(International)**	√			Clauson, Per	Novo Nordisk	Both	18+	N/S	435	October-04	N/S	Adult	The purpose of this study is to test whether insulin detemir is a safe and at least as effective alternative to insulin glargine for the control of blood glucose in basal/bolus therapy in patients with type I diabetes.
Safety and Efficacy of Insulin Aspart Versus Insulin Lispro in Insulin Pumps in Children and Adolescents With Type 1 Diabetes			√	Howard, Campbell	Novo Nordisk	Both	3 to 18	N/S	280	October-04	N/S	Child	To compare the safety and efficacy of Insulin Aspart (NovoLog®) and Insulin Lispro (Humalog®) delivered by CSII in children and adolescents with type 1 diabetes.
TRANSPLANTATION													
Immunomodulation for Islet Transplantation in Diabetes	√			Alejandro, Rodolfo	NIDDK	Both	18 to 65	N/S	Enrollment # not specified	July-00	December-01	Adult	To determine if islet cell transplantation in patients with Type 1 Diabetes Mellitus provides constant normal blood glucose levels.
A European Multicenter Open-Label Randomised Trial to Evaluate the Efficacy and Safety of Sirolimus and Tacrolimus Compared to MMF and Tacrolimus With Short-Course Induction Therapy, Short-Term Steroids Application in De Novo SPK Transplanted Diabetic Patients **(International)**			√	Squifflet, Jean-Paul	EUROSPK Study Group	Both	18 to 55	N/S	228	February-02	May-08	Adult	To determine and compare the efficacy of Tacrolimus/Rapa versus Tacrolimus/MMF-based immunosuppression (in conjunction with initial short-term steroids and polyclonal antibody administration) in Type 1-diabetic patients undergoing simultaneous pancreas/kidney allograft transplantation; and to evaluate the safety of Tacrolimus/Rapa versus Tacrolimus/MMF in terms of drug-related complications and overimmunosuppression-associated complications, particularly under monitoring of the pharmacokinetic profile of all drugs administered.