OPEN STUDIES FOR DIABETES MELLITUS TYPE 1

Title	Type	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
PREVENTION/REVERSAL											
A Randomised, Double-Blind, Placebo-Controlled Trial of Intranasal Insulin (1.6mg and 16mg) in Children and Young Adults at Risk of Type 1 Diabetes: Intranasal Insulin Trial II **(Australia)**	1	Harrison, Leonard	Melbourne Health Diabetes Vaccine Development Centre	Both	4 to 30	N/S	264	February-06	January-13	Both	To determine if intranasal insulin can protect beta cells and stop progression to diabetes in individuals who are at risk.
TRIGR - Trial to Reduce IDDM in the Genetically at Risk **(International)**	1	Akerblom, Hans	NICHD	Both	newborn to 7	N/S	2,032	March-02	December-16	Child	To determine whether weaning to a possibly protective infant formula decreases these children's chances of developing diabetes - as it does in the animal models for diabetes.
Intranasal Insulin for Prevention of Type 1 Diabetes in Children Carrying Increased HLA -Conferred Genetic Risk **(Finland)**	1	Simell, Olli	University of Turku Oulu University Hospital	Both	1 to 15	N/S	240	August-97	November-07	Both	Hypothesis is that intranasal insulin delays or prevents development of clinical type 1 diabetes. The primary outcome measure is development of clinical diabetes, but serum concentrations of autoantibodies, responses to intravenous glucose tolerance test and possible side effects of therapy are also closely monitored.
A Phase 2/3, Randomized, Double-Blind, Multicenter, Multinational, 4-Arm, Controlled, Dose-Ranging Study to Evaluate Efficacy and Safety of MGA031, a Humanized, FcR Non-Binding, Anti-CD3 Monoclonal Antibody, in Children and Adults With Recent-Onset Type 1 Diabetes Mellitus	1	Aronoff, Stephen	MacroGenics	Both	8 to 30	N/S	530	October-06	N/S	Both	To assess the efficacy, tolerability, and safety of MGA031 when administered according to 3 different MGA031 dosing regimens in children and adults with recent-onset (diagnosis within past 6 weeks) Type 1 diabetes mellitus.
PREVENTION OF COMPLICATIONS											
Improving Blood Pressure Management in Patients With Diabetes: SCRIP-HTN **(Canada)**	1	Tsuyuki, Ross	University of Alberta	Both	18+	N/S	220	May-05	December-06	Adult	To test whether a community pharmacist and nurse team can improve blood pressure control in people with diabetes and hypertension.
TREATMENT/MANAGEMENT/BEHAVIORAL											
The Effect of Insulin Analogues and Human Insulin on the Incidence of Severe Hypoglycaemia in Hypoglycaemia Prone Type 1 Diabetic Patients **(Denmark)**	1	Tarnow, Lise	Steno Diabetes Center	Both	18+	N/S	250	October-06	May-10	Adult	To evaluate the effects of insulin analogue and human insulin on incidence of severe hypoglycaemia in type 1 diabetic patients prone to hypoglycaemia.
Non-Significant Risk Investigational Device Study of the Wireless GlucoMON™ Glucose Meter Accessory and Real-Time Blood Glucose Alerts as an Enabling Technology for People Who Team Manage Diabetes	1 and 2	McMahon, Kevin	Diabetech	Both	Age not specified	N/S	1,000	April-06	March-08	Age not specified	To test the GlucoMON glucose meter accessory device and the real-time wireless alerts feature which automatically sends to a specific team of interested caregivers whom the patient selects and the effects of real-time alerts in the management of diabetes.
Family Management of Type 1 Diabetes in Children (trial not open but listed as recruiting)	1	Simons-Morton, Bruce	NICHD	Both	9 to 15	N/S	480	January-06	January-09	Child	To test the effectiveness of a practical, low-cost, low-intensity behavioral intervention that can be integrated directly into diabetes clinic routines.
A Phase 3, Open-Label, Parallel-Group Study to Evaluate the Efficacy of Preprandial Human Insulin Inhalation Powder (HIIP) Compared to Preprandial Injectable Insulin in Patients With Type 1 Diabetes Mellitus	1	Eli Lilly	Eli Lilly	Both	18+	N/S	320	August-06	April-08	Adult	To test for non-inferiority of preprandial HIIP [also known as AIR(R) Inhaled Insulin Powder][AIR(R) is a registered trademark of Alkermes,Inc.] compared with preprandial injectable insulin (insulin lispro) with respect to HbA1c after 6 months of treatment in patients with type 1 diabetes mellitus.
Pulmonary Outcomes Within a 2-Year Period in Subjects With Diabetes Mellitus Treated With Technosphere /Insulin or Usual Antidiabetic Treatment and in Subjects Without Abnormalities in Glucose Control **(International)**	1 and 2	Mankind	Mankind	Both	18 to 70	N/S	2464	June-06	August-06	Adult	Pulmonary Safety in Diabetics with T/I.
Comparison of Efficacy and Safety of Insulin Detemir Once or Twice Daily in a Basal-Bolus Regimen With Insulin Aspart in Patients With Type 1 Diabetes **(Europe)**	1	Champigneulle, Agnes	Novo Nordisk	Both	18 to 70	N/S	750	June-05	N/S	Adult	To compare the efficacy (reduction in HbA1c and in blood glucose levels) of insulin detemir once daily injection compared to insulin detemir twice daily injection 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 side effects).
A Crossover, Multicentre, Randomised Trial Comparing the Effect on the Control of Blood Glucose Concentration of Insulin Glargine and Insulin Detemir, Combined With Insulin Glulisine, Used as a Bolus, in Type 1 Diabetic Patients **(France)**	1	Couderc, M	Sanofi-Aventis	Both	18+	N/S	Enrollment # not specified	N/S	N/S	Adult	To compare the variability of fasting capillary blood glucose concentration, observed with insulin glargine combined with insulin glulisine and with insulin detemir combined with insulin glulisine, in type 1 diabetics.

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Inhaled Mealtime Insulin With the AERxÂ® iDMS Versus Subcutaneous Injected Insulin Aspart Both in Combination With Insulin Detemir in Type 1 Diabetes: A 104 Week, Open-Label, Multicenter, Randomised, Parallel Trial (Followed by a Twelve-Week Re-Randomised Extension) To Investigate Safety and Efficacy **(USA and Canada)**	1	Sonnenberg, Gabriele	Novo Nordisk	Both	18+	N/S	546	May-06	N/S	Adult	To compare the efficacy (reduction in HbA1c and blood glucose) and pulmonary safety (pulmonary function, chest x-rays) of mealtime inhaled insulin with subcutaneous insulin aspart both in combination with insulin determir in Type 1 Diabetes.
Non-Significant Risk Investigational Device Study of the Wireless GlucoMON™ Glucose Meter Accessory and Real-Time Blood Glucose Alerts as an Enabling Technology for People Who Team Manage Diabetes	1	McMahon, Kevin	Diabetech	Both	Age not specified	N/S	1,000	April-06	March-06	N/S	To compare a new wireless device and Internet-based automated data management csystem to existing methods of sharing data amongst an interested care team.
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	1	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.
A Prospective, Multi-Center, Open-Label, Randomized, Controlled Clinical Trial Comparing the Efficacy and Safety in Subjects With Type 1 Diabetes Receiving Subcutaneous Basal Insulin and Prandial Inhalation of Technosphere/Insulin Versus Subcutaneous Basal and Prandial Insulin Over a 52-Week Treatment Period and a 4-Week Follow Up **(International)**	1	Gash, David	Mankind	Both	18 to 80	N/S	564	February-06	January-08	Adult	To determine the safety and efficacy of inhaled insulin in the treatment of type 1 diabetes.
A Crossover, Multicentre, Randomised Trial Comparing the Effect on the Control of Blood Glucose Concentration of Insulin Glargine and Insulin Detemir, Combined With Insulin Glulisine, Used as a Bolus, in Type 1 Diabetic Patients **(France)**	1	Couderc, M	Sanofi-Aventis	Both	18+	N/S	Enrollment # not specified	N/S	N/S	Adult	To compare the variability of fasting capillary blood glucose concentration, observed with insulin glargine combined with insulin glulisine and with insulin detemir combined with insulin glulisine, in type 1 diabetics.
TRANSPLANTATION											
Alemtuzumab Versus Thymoglobulin Induction Therapy in Kidney and Pancreas Transplantation	1	Stratta, Robert	Wake Forest University Baptist Medical Center	Both	18 to 75	N/S	225	February-05	October-08	Adult	To compare the effects of two different anti-rejection medications (alemtuzumab and rabbit anti-thymocyte globulin) given by vein to see which is better, with a standard combination of anti-rejection medications given by mouth in kidney and pancreas transplant patients