LPS14347

Principal Investigator: Neil J. Fraser, MD, FACP

Condition: Type 2 Diabetes
Drug: Toujeo/insulin glargine
Official Title: A randomized, open-label, parallel group real world pragmatic trial to assess the clinical and health outcomes of Toujeo® compared to commercially available basal insulins for initiation of therapy in insulin naïve patients with uncontrolled type 2 diabetes mellitus
Sponsor: Sanofi
Purpose: This study is to compare Toujeo® to other commercially available basal insulins at 6 and 12 months after initiating insulin therapy in patients who are insulin naïve, in reducing the risk of hypoglycemia and changes in HbA1c, fasting plasma glucose, and body weight.

Inclusion Criteria:

Adult patients with type 2 diabetes, diagnosed for at least one year
Currently taking two diabetic medications for greater than one year
HbA1c > 8.0% and < 11.0%

Exclusion Criteria:

Type 1 diabetes mellitus
Use of any product containing insulin for more than 3 months

If interested please contact: Ashley Hopkins, BS, CCRC at 248-312-0025 x 6104
Abigail Dermyer, MS at 248-312-0025 x 6107

THEMIS

Principal Investigator: Neil J. Fraser, MD, FACP

Condition: Prevention of stroke or heart attack in Type II Diabetes Mellitus patients
Drug: Ticagrelor or placebo
Official Title: A Multi-national, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Effect of Ticagrelor Twice Daily on the Incidence of Cardiovascular Death, Myocardial Infarction, or Stroke in Patients with Type II Diabetes Mellitus
Sponsor: AstraZeneca
Purpose: The primary objective of this study is to compare the effect of long-term treatment with Ticagrelor 60 mg twice daily verses placebo for the prevention of major cardiovascular events (heart attack, stroke or cardiovascular death) in patients with Type II Diabetes Mellitus at high risk of cardiovascular events, but without a history of a heart attack or stroke.
Inclusion Criteria:
Diagnosed with Type II Diabetes Mellitus defined by the ongoing glucose lowering drug treatment prescribed by a physician for treatment of Type II Diabetes Mellitus since at least 6 months prior to Visit 1.
High Risk of CV events, defined as history of percutaneous coronary intervention or coronary artery bypass or angiographic evidence of one 50% lumen stenosis of at least one coronary artery
Exclusion Criteria:
Previous heart attack
Previous stroke
Planned use of prescribed blood thinners or daily use of aspirin.

If interested please contact: Candice Hessler, CCRP at 248-312-0025 x 6106
Ashley Hopkins, BS, CCRC at 248-312-0025 x 6104
Abigail Dermyer, MS at 248-312-0025 x 6107
Kelsey Hug, BS at 248-312-0025 x 6108

C. diff Vaccine

Principal Investigator: Neil J. Fraser, MD, FACP

Condition: Two hospitalizations in past year or planned upcoming hospitalization for surgery
Drug: *C. difficile* toxoid vaccine
Official Title: Efficacy, Immunogenicity, and Safety Study of *Clostridium difficile* Toxoid Vaccine in Subjects at Risk for *C. difficile* Infection
Sponsor: Sanofi Pasteur
Purpose: This study is being conducted to develop a vaccine against primary symptomatic *Clostridium difficile* infection in at-risk individuals.
Inclusion Criteria:

≥ 50 years of age
Had a least two stays and had antibiotics in the past 12 months
Or
Anticipated to have an in-patient hospitalization for a planned surgical procedure

Exclusion Criteria:

Receipt of any vaccine in the four weeks before the trial (except flu and pneumonia)
Anticipated or current kidney dialysis
History of gastrointestinal surgery for malignancy
History of irritable bowel syndrome, inflammatory bowel disease, colostomy, or small or large intestine bowel surgery where resection was performed
Chemo or radiation therapy in the last 6 months, long term corticosteroid use in the past 3 months
Known hypersensitivity to any vaccine component

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Abigail Dermyer, MS at 248-312-0025 x 6107

MET56

Principal Investigator: Neil J. Fraser, MD, FACP

Condition: Vaccination against Meningitis
Drug: MenACYW conjugate vaccine: Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine
Official Title: Phase III, modified double-blind, randomized, parallel-group, active-controlled, multi-center trial to compare the immunogenicity and describe the safety of a booster dose of MenACYW conjugate vaccine to a licensed vaccine in quadrivalent meningococcal conjugate vaccine-primed adolescents (≥15 to ≤18 years) and adults (≥18 years) in the United States
Purpose: This study is being conducted to demonstrate the non-inferiority of the MenACYW booster vaccine compared to the administration of the booster dose of Menactra® in subjects who were first vaccinated with a quadrivalent meningococcal conjugate vaccine 4-10 years before the booster dose.
Inclusion Criteria:

Age ≥ 15 years
Documentation of receiving a quadrivalent meningococcal conjugate vaccine 4-10 years ago

Exclusion Criteria:

Receipt of any vaccine in the four weeks before the trial
Receipt of immune globulins, blood, blood-derived products in the past 3 months
Immunodeficiency, receipt of immunosuppressive therapy (chemo/radiation)
Long term corticosteroid use
History of meningococcal infection
Known hypersensitivity to vaccine components, history of life-threatening reaction to vaccine
History of Arthus-like reaction after vaccination with a tetanus toxoid-containing vaccine
History of Guillain-Barre syndrome
Current drug or alcohol addiction
Bleeding disorder or receipt of anticoagulants in the 3 weeks before inclusion
Receipt of oral or injectable antibiotics within 72 hours prior to first visit

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Ashley Hopkins, BS, CCRC at 248-312-0025 x 6104
Abigail Dermyer, MS at 248-312-0025 x 6107
Kelsey Hug, BS at 248-312-0025 x 6108

LIRA-PRIME

Principal Investigator: Neil J. Fraser, MD, FACP

Condition: Type 2 Diabetes Mellitus
Drug: Victoza vs. oral antidiabetic drugs
Official Title: Efficacy in controlling glycaemia with Victoza®(liraglutide) as add-on to metformin vs. OADs as add-on to metformin after up to 104 weeks of treatment in subjects with type 2 diabetes inadequately controlled with metformin monotherapy and treated in a primary care setting
Sponsor: Novo Nordisk
Purpose: This study is to compare the efficacy of Victoza® as add-on to metformin verses oral antidiabetic drugs in addition to metformin in patients with type 2 diabetes mellitus. Patients with an HbA1c between 7.5-9.0% will be monitored for changes from baseline weight, fasting plasma glucose, and HbA1c.

Inclusion Criteria:

Adults with type 2 diabetes mellitus diagnosed at least 90 days before screening
Must be on a stable dose of metformin ≥1500 mg or maximum tolerated dose within 60 days prior to screening
Must have a HbA1c between 7.5-9.0%

Exclusion Criteria:

Females who are pregnant, intend to become pregnant, or breastfeeding
Treatment with any diabetic medication other than metformin in the 60 days before screening

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Abigail Dermyer, MS at 248-312-0025 x 6107
Kelsey Hug, BS at 248-312-0025 x 6108

TYPE II DIABETIC STUDY

Principal Investigator: Neil J. Fraser, MD, FACP

Condition: Type II Diabetes Mellitus
Drug: DS-8500a, sitagliptin, and placebo
Official Title: A Randomized, Double-Blind, Placebo-Controlled with Active Comparator, 12-Week Study of DS8500a in Subjects with Type 2 Diabetes Mellitus on Metformin.
Sponsor: Daiichi Sankyo
Purpose: The primary objective is to evaluate change in hemoglobin A1c (HbA1c) from baseline to Week 12 with DS-8500a compared with placebo in subjects with T2DM.
Inclusion Criteria:
Diagnosed with Type 2 Diabetes Mellitus as defined in the American Diabetes Association Standards of Medical Care in Diabetes 2015
Male of female >/= 18 and </= 70 years of age
On stable (>/= 8 weeks) metformin monotherapy >/= 1000 mg/day.
Screening HbA1c >/= 7.0% and </= 10%.
Exclusion Criteria:
History of Type I Diabetes and/or history of ketoacidosis
History of insulin use for > 2 weeks within 2 months prior to the Screening Visit
Subjects after bariatric surgery or any gastric bypass or planning to have such a procedure during the study
History of myocardial infarction, stroke or any revascularization procedure during the 6 months prior to the Screening Visit or planned vascular procedures during study period
History of Congestive Heart Failure
No diabetes medication other than metformin, systemic corticosteroids or Rosuvastatin > 20 mg for 8 weeks prior to screening and throughout the study period
Any history of malignancy other than basal cell carcinoma within the past 5 years

If interested please contact: Ashley Hopkins, BS, CCRC at 248-312-0025 x 6104
Kelsey Hug, BS at 248-312-0025 x 6108

SPIRE 1

Principal Investigator: Neil J. Fraser, MD, FACP

Condition: Cardiovascular Disease
Drug: Bococizumab (PF-04950615) or placebo
Official Title: Phase 3 Multi-center, Double-blind, Randomized, Placebo-controlled, Parallel Group Evaluation of the Efficacy, Safety, And Tolerability Of Bococizumab (Pf-04950615) In Reducing The Occurrence Of Major Cardiovascular Events in High Risk Subjects.
Sponsor: Pfizer
Purpose: This study evaluates the PCSK9 inhibitor, Bococizumab (PF-04950615; RN316), compared to placebo, in reducing the occurrence of major cardiovascular events, including cardiovascular death, myocardial infarction, stroke, and unstable angina requiring urgent revascularization, in high risk subjects who are receiving background lipid lowering therapy and have cholesterol laboratory values of LDL-C >/= 70 mg/dL (1.8 mmol/L) and < 100 mg/dL (2.6 mmol/L) or non-HDL-C >/= 100 mg/dl (2.6 mmol/L) and < 130 mg/dL (3.4 mmol/L).
Inclusion Criteria:
Must be on background lipid lowering treatment
Must be at high risk of a CV event
Must have an LDL-C >/= 70 mg/dL (1.8 mmol/L) and < 100 mg/dL (2.6 mmol/L) or non-HDL-C >/= 100 mg/dl (2.6 mmol/L) and < 130 mg/dL (3.4 mmol/L).
Exclusion Criteria:
An LDL-C <70 mg/dL (1.8 mmol/L) or >/= 100 mg/dL (2.6 mmol/L) or non-HDL-C < 100 mg/dl (2.6 mmol/L) and >/= 130 mg/dL (3.4 mmol/L).
Planned coronary (PCI or CABG) or other arterial revascularization.
New York Heart Association Class IV congestive heart failure or left ventricular ejection fraction < 25% by cardiac imaging.
Chronic renal insufficiency with creatinine clearance of <30 ml/min/1.73m^2 by MDRD formula or with end state renal disease on dialysis.
History of hemorrhagic stroke.
Prior exposure to Bococizumab or other investigational PCSK9 inhibitor.

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