

NCT NUMBER: NCT02536248

DRUG NAME: SITAGLIPTIN

STUDY TITLE: EFFECTS OF SITAGLIPTIN THERAPY ON THE KINETICS OF MARKERS OF LOW-GRADE INFLAMMATION AND CELL ADHESION MOLECULES IN PATIENTS WITH TYPE 2 DIABETES

INVESTIGATORS: Patrick Couture MD, FRCPC, PhD

André J. Tremblay, PhD

Benoît Lamarche, PhD

PROTOCOL DATE: February 12<sup>nd</sup>, 2015

This protocol is **CONFIDENTIAL** and no person is authorized to make it public or modify it without the written permission of Dr. Patrick Couture. This restriction on disclosure will apply to all future information provided about this study which is indicated as privileged or confidential.

**SAMPLE SIZE, STATISTICAL ANALYSIS, DATA ANALYSIS AND EXPECTED RESULTS**

Data will be analyzed using a scheme for repeated measures. This power analysis is based on our previous results showing that treatment with sitagliptin 100 mg/d in similar diabetic subjects was associated with a 7.8% and 9.3% reduction in postprandial response of apoB-48 and VLDL-C, respectively (manuscript submitted to Diabetes, Obesity and Metabolism). A conservative power calculation was conducted while assuming that the standard deviation of the difference TRL kinetic parameters between each treatment phase will be 2-fold greater than the mean treatment effect. Power calculations indicated that a total of 20 patients entering this study with a desired power of 80% will allow us to detect a treatment difference at a one sided 5%, if the true difference between the treatments is 9%. As mentioned above, this is based on the assumption that the standard deviation of the difference between placebo and sitagliptin treatment is 18%; i.e. 2-fold greater than the treatment effect per se. We are therefore confident that the present study design will allow us to obtain novel and scientifically rigorous data on the effects of sitagliptin on the kinetics of serum amyloid A in type 2 diabetic patients.

Since the present study (NCT02536248) is a substudy of the main research project entitled: “**A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, CROSSOVER STUDY TO EVALUATE THE EFFECTS OF SITAGLIPTIN ON THE KINETICS OF TRIGLYCERIDE-RICH LIPOPROTEINS APOLIPOPROTEIN B48 AND APOLIPOPROTEIN B100 IN PATIENTS WITH TYPE 2 DIABETES**” (NCT01334229), the kinetics of Serum amyloid A have been analyzed with the same statistical approach.

Furthermore, there was no Informed Consent Form because participants had already signed it in the previous study.