The LIPL-PLATELET Study

LIPid paneLs And PLATELET activity in coronary heart disease

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Abstract

At present lipid variables are evaluated in the fasting state. Measuring the lipid panel in the fasting state can be inconvenient as the patients go through fasting period of up to 12 hours [1]. This may not only aggravate their compliance but also exposes the diabetic patients at the risk of hypoglycemia. In reality, most of patients find themselves in a non-fasting state for the whole day. Hence, the process of atherosclerosis and thrombosis occurs mostly under the influence of non-fasting lipids. Therefore, it would be more accurate for cardiovascular risk evaluation to measure the lipid panel in the non-fasting state. Platelet activity plays a key role in atherosclerosis and thrombus development and it is a well known fact that lipids have an effect on platelet activity [2–7]. The aim of this study is to investigate the change in the lipid profile, in haemostasis, and platelet activity after fat loading in different study population: 1. Patients with stable coronary artery disease (sCAD) on optimal lipid lowering therapy and indication for PCSK9-inhibitors (PCSK9i; alirocumab or evolocumab) (Group A), 2. Patients with sCAD on high-dose statins (Group B) and 3. Age and sex-matched healthy volunteers (Group C). Lipid variables, biomarkers of thrombosis as well as platelet function and platelet variables associated with platelet activation will be assessed. Blood collection will be performed in the fasting state and three and five hours after a defined oral fat tolerance test. As fat loading a milkshake with 90g fat will be consumed.

In group A patients will receive fat loading before start of PCSK9 inhibitor administration (visit 1) and 3 months after chronic PCSK9i.

A change of platelet activation either measured as platelet function or a change of circulating monocyte-platelet aggregates and platelet variables associated with platelet activation in the fasting and non-fasting state in patients with different lipid lowering therapy will be investigated.

Report

The LIPL PLATELET Study is the study, which aims to investigate the effect of PCSK9-Inhibitors on a platelet activity. Therefore, an inclusion of patients with cardiovascular disease treated with different lipid-lowering therapy is needed in order to prove a different change of platelet activity in fasting and non-fasting state.

The LIPL PLATELET Study was approved by the Ethics committee of the City Vienna on 28.06.2018. The inclusion of the patients into this study began on 01.07.2018. Initially, an inclusion of 63 patients with 21 patients pro group was planned. However, because the prescription of PCSK9-Inhibitors has its strict indications, it seems impossible to include the original amount of patients in the group with coronary heart disease on PCSK9-Inhibitors (Group A) within a reasonable time period. Therefore, we decided to investigate 10 patients pro group. Since there was no study, which investigated the effect of PCSK9-Inhibitors in fasting and non-fasting state and this is a hypothesis-generating study, this may be the optimal size of the study population.

Until now totally 21 patients were included in the study (Group A: n=1, Group B: n=10, Group C: n=10). Hence, only the inclusion of patients with PCSK9-Inhibitors therapy is necessary. No adverse event or serious adverse event was reported. The inclusion in the Group A is difficult due to strict inclusion criteria.

The estimated length of inclusion in the study is at least one year. The patient´s visits will be finished within the next 15 months. Afterward, a data bank will be summarized for the further statistical analyses and the results will be summed up and submitted to be published in scientific journals.