A prospective study to evaluate the efficacy of a standardized low calorie diet according to PNPLA3 genotype in patients with Non Alcoholic Fatty Liver Disease (NAFLD) – 2 months data (interim analysis)

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Background
With a prevalence of 30% in the Western population, NAFLD is one of the most common liver diseases which also increases the risk of Non Alcoholic Steatohepatitis (NASH), fibrosis, cirrhosis and even hepatocellular carcinoma. NAFLD is also referred to as hepatic manifestation of the metabolic syndrome and therefore is strongly associated with the aggravation of diabetes and cardiovascular disease. PNPLA3 is a major risk factor for hepatic steatosis. Especially G allele increases liver fat content and leads to a higher susceptibility for disease progression. Lifestyle modification through dietary and exercise interventions with the main objective of weight reduction represents the cornerstone for treating patients with NAFLD. HEPAFAST® is a protein shake, developed for the treatment of fatty liver disease. Besides whey protein HEPAFAST® is characterized by the addition of different liver protective substances, such as β-glucan, cholin, taurin and long-chained omega-3 fatty acids.

Aim
Aim of this study is to analyze the efficacy of a standardized low calorie protein shake diet (HEPAFAST®, Bodymed, Kiel, Germany) specifically developed for patients with NAFLD and the influence of PNPLA3 genotypes on treatment outcome.

Methods
In this study 81 non cirrhotic patients are included and stratified according to PNPLA3 genotype (27 patients per group; CC, CG, GG). All patients receive a low calorie diet (max. 1000 kcal per day) with HEPAFAST® protein shakes for 2 weeks and subsequently follow a low glycemic and insulimic (LOGI) diet for another 6 weeks (EOT). Compliance is monitored with food logs. All patients are seen longitudinally for four time points (baseline, week 2, month 2, 6 months-follow up). Liver fat content measured by Fibroscan® CAP is used as primary endpoint.

Liver fat content is assessed by an independent/blinded investigator with Fibroscan® CAP at each study visit. Additionally liver stiffness (kPa), fatty liver index (FLI), waist circumference (WC), BMI, triglycerides (TG), GGT and vitamin D are analyzed.

Conclusion
A low calorie diet with HEPAFAST® shakes is a very effective strategy to significantly lower liver fat content in NAFLD patients. Furthermore it leads to a significant drop of liver stiffness. Implementation of a low glycemic and insulimic diet (LOGI) further improves results. There seems to be no better response to a standardized low calorie diet in patients carrying the PNPLA3 G-allele.