*GastroFlow: Investigation of the gastrointestinal blood flow in patients with postprandial hypotension*

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**Title: Investigation of the gastrointestinal blood flow in patients with postprandial hypotension**

**Approved ethical committee ID**:

**Background**: In healthy men endogenous glucose-dependent insulinotropic polypeptide (GIP) contribute to the increased abdominal blood flow in the superior mesenteric artery after the ingestion of glucose. Previous studies have established that the GIP receptor is downregulated in patient with

type 2 diabetes. With the use of flow sensitive magnetic resonance imaging (MRI), we investigated the effect of endogenous GIP on the gastrointestinal blood flow in patients with postpandial hypotension.

**Aim**: The aim of this study is to investigate and describe the changes in blood flow and oxygen tension in the vessels superior mesenteric artery, celiac trunk, arteria hepatica, and vena portae during and after ingestion of glucose or water in patients with postpandial hypotension. Furthermore, we will investigate the effect of endogenous GIP on the postprandial blood flow in patients with postprandial hypotension with an infusion of the GIP receptor antagonist GIP(3-30)$NH_2$ (1,000 pmol/kg/min).

**Hypothesis**: The hypothesis of this study is that the intake of glucose will result in a redistribution of blood that increases the blood flow to the intestines and that antagonization of GIP receptor postprandially will affect the redistribution of blood flow in patients with postprandial hypotension.

**Design**:
Randomized, placebo controlled, crossover, single blind design in 15 patients with postprandial hypotension and 15 healthy matched controls.

**Baseline information:**
A description of the baseline measured will be presented in a table, including the following measures: Age, Weight, Height, BMI, Hemoglobin, Leucocytes, Vitamin D, Fasting glucose, HbA1c, Sex, and Blood pressure. The data will be presented in Median and range.

**Statistical analysis and graphs**:
The flow data is analyzed in Rs studio by a linear mixed model, that pairs the data, and compared the interventions after steady state of the infusion of GIPR antagonist. The primary statistical analysis will be done between the two interventions: GIPR-antagonist infusion + oral glucose ingestion and Saline + oral glucose ingestion. Furthermore, the data will be presented in GraphPad Prism 10. A data table will present the flow measurements of each intervention, including mean and 95% confidence intervals.

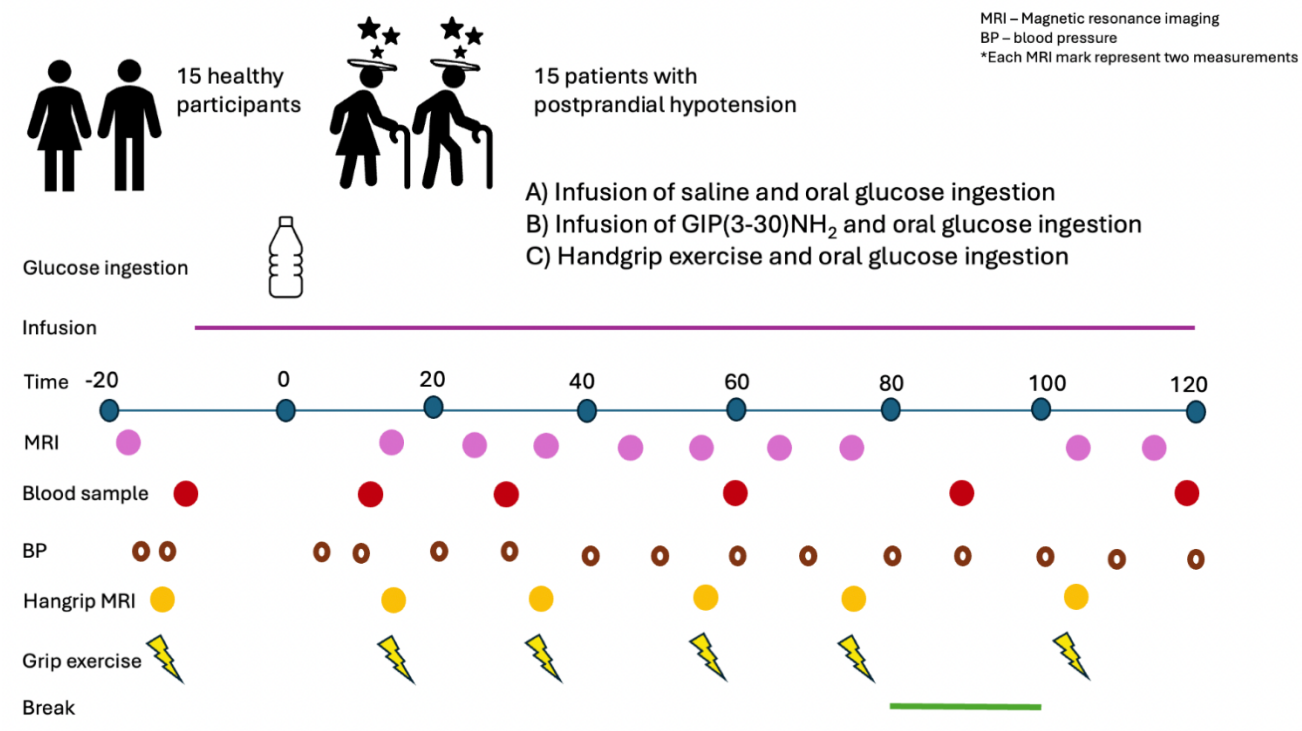
**Criteria:**
Inclusion = Postpradial hypotenison
Exclusion = Not MRI-compatible implants, claustrophobia, abnormal kidney or liver function, anemia, planned weight loss or change in diet, hypertension, other conditions that could be expected to affect the primary or secondary outcomes

**Interventions:**

1) Saline infusion + oral glucose tolerance test (OGTT)
4) GIP(3-30)$NH_2$ infusion + OGTT
3) Hand grip exercises + OGTT

**Methods and outcomes**: Phase-contrast magnetic resonance imaging (PC-MRI) is used to calculate blood flow in the four described vessels during the infusion of either saline or GIP receptor antagonist. The main outcome of the study is *blood flow in superior mesenteric artery*. On each study day, 12 MRI scans are performed (-20 min to 120 min after oral fluid intake) and six blood samples. Blood

glucose is measured bedside on whole blood. The blood samples collected are kept for analysis of GIP(1-42), GIP(3-30)$NH_2$, glucagon, insulin, and C-peptide.




**Adverse event:**

All adverse events (AEs) or serious adverse event (SAE) are reported throughout the whole study period, any adverse event reported will be informed to the ethical committee responsible for the study. All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate case report form. Information to be collected includes event description, time of onset, qualified medical professional's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.