

Mechanisms and Clinical Course of Endoscopic Overstitch Procedure in Patients with Gastric Bypass and Late Dumping Syndrome (the MECCEO Study).

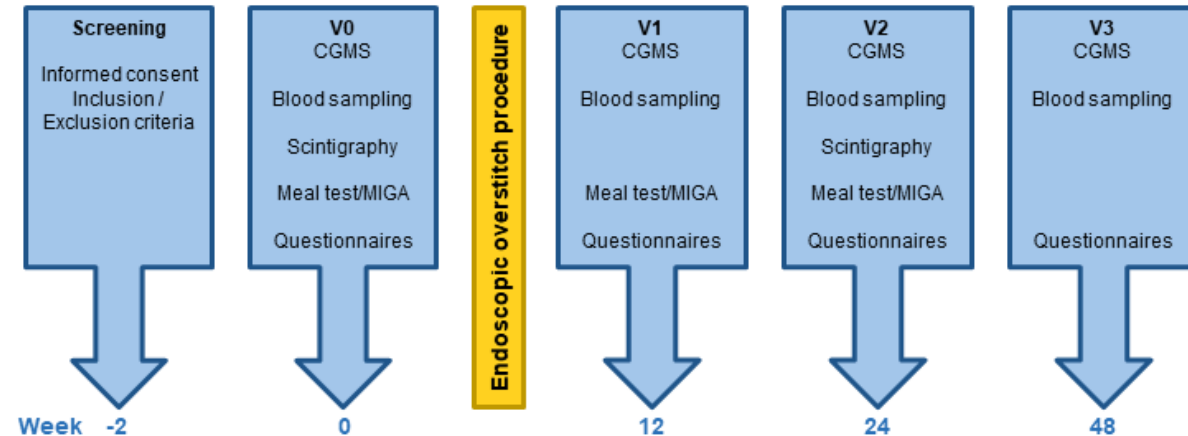
Primary endpoint:

- Occurrence of hypoglycemia after standardized mixed meal test (MMT)

Secondary endpoints:

- Occurrence and severity of hypoglycemia after MMT in relation to measured insulin-/C-peptide-, GI-hormones-, glucagon-levels and gastric emptying 3, 6 and 12 months after endoscopic overstitch procedure.
- Changes in parameters, assessed by continuous-glucose monitoring system (CGMS)
- Signs and symptoms of late dumping syndrome
- Changes of bile acid-secretion
- Change of weight
- Patient reported outcomes

Study Flow Chart



CGMS: continous glucose monitoring system
MIGA: measurement of intestinal glucose absorption

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Inclusion criteria:

- Adult male or female, age ≥ 18 years, informed consent obtained
- Diagnosis of LDS after gastric bypass surgery by presence of at least 1 of the following conditions:
 - history of ≥ 1 episode(s) of severe postprandial hypoglycemia (defined as the occurrence of neuroglycopenia, coma or the necessity of assistance for treatment of the hypoglycemia)
 - history of ≥ 1 episode(s) of severe postprandial hypoglycemia and the presence of Whipple triad
 - provoked severe hypoglycemia by standardized meal test
- Diagnosis of early dumping syndrome (facultative)
- Regular follow-up with the nutritionist guaranteed

Exclusion criteria:

- Patients with TORe* in the past
- Patients with diabetes mellitus and therapy with the following medicaments in the last 30 days before inclusion: DPP-IV inhibitors, GLP-1 receptor agonists, sulfonylureas, insulin
- Treatment with oral glucocorticoids
- Treatment with acarbose in the last 3 days before inclusion
- Treatment with diazoxide in the last 8 days before inclusion
- Treatment with long-acting somatostatin analogues in the last 12 weeks before inclusion
- Pregnancy and breast feeding
- History of inflammatory bowel disease

* transoral outlet reduction (overstitch)