PBH-MASTER study: Post Bariatric Hypoglycemia Medical And Surgical Treatment Evaluation in Retrospect study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22335

Source
NTR

Brief title
PBH-MASTER

Health condition

post bariatric hypoglycemia, RYGB, OAGB

Sponsors and support

Primary sponsor: Medical Center Leeuwarden
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

- Number of drugs currently used for PBH: 1, 2, 3, more

Then for each drug:
- Name of drug
- Number in line of treatment: first, second, third, etc.
- Replacement or addition
- Daily total dosage used
- Start date (month-year)
- Treatment effect:
objective : 1. resolution of severe hypoglycemia (neuroglycopenia or glucose (SMBG) < 3.0 mM or blinded continuous glucose monitoring (cgm) 2.8 mM), >50% resolution, < 50% resolution, 0-20% resolution
2. number of hypoglycemic events per week/month for which action is needed
subjective :1. As documented in the file: semi-quantitive:
complete resolution, near-complete, acceptable decrease, not enough decrease, no decrease in hypo-episodes
2. Patient questionnaire: see questionnaire

Secondary outcome

- Side effects: no, yes-acceptable, yes-not acceptable
Kind of side effect
Current use: yes, no-date stopped (month-year),

Study description

Background summary

Bariatric surgery is currently the only therapy leading to sustained significant weight loss together with high percentages of remission of diabetes and other co-morbidities.
These impressive beneficial effects however can come at a price. One of the side effects is the development of postprandial hyperinsulinemic hypoglycemia, also called post bariatric hypoglycemia, PBH. Treatment approaches for PBH include dietary modifications, pharmacologic interventions and, possibly, surgical re-intervention or continuous tube feeding. Literature on the effect of treatment of PBH is scarce. The aim of this study is to evaluate the effect of different types of treatment for PBH, including medical therapy and/or surgical procedures, in terms of efficacy, tolerability and side effect in daily life. Objective : To retrospectively evaluate the effect of current medical treatment and the four surgical procedures for PBH on the resolution of hypoglycemic events and side effects in daily practice.Patients after gastric bypass surgery with PBH and with hypoglycemic episodes despite adequate dietary advice who were referred to either an endocrinologist or a surgeon from the Centrum Obesity North-Netherlands (CON) at Medical Center Leeuwarden, University Hospital Groningen and AmsterdamUMC. Inclusion criteria : (Roux-en-Y gastric bypass) RYGB or OAGB (mini-gastric bypass), documented hypoglycemia with self-measured glucose (SMBG) < 3.0 mM, blinded continuous glucose monitoring (cgm) 2.8 mM or Meal Test (< 3.0 mM, neuroglycopenic symptoms with resolution of symptoms after normalization of

blood glucose. Hypoglycemic episodes despite adequate dietary advice and interfering with daily activities, socially and/or work-related and willingness to participate. Study design : Retrospective observational study combined with a short questionnaire.

Study objective

none applicable

Study design

see primary and secondary endpoints : all data will be retrieved from the medical file uptill june 1st 2021. The questionnaire will be send to the willing participants in june 2021

Intervention

none

Contacts

Public
Medisch Centrum Leeuwarden
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Eligibility criteria

Inclusion criteria

- (Roux-en-Y gastric bypass) RYGB or OAGB (mini-gastric bypass)
- documented hypoglycemia with self-measured glucose (SMBG) < 3.0 mM, blinded continuous glucose monitoring (cgm) 2.8 mM or Meal Test (< 3.0 mM)
- neuroglycopenic symptoms: behavioral changes, confusion, loss of consciousness, seizures
- symptom resolution after normalization of blood glucose
- hypoglycemic episodes despite adequate dietary advice* and interfering with daily activities, socially and/or work-related

- willingness to participate

Exclusion criteria

- diabetes or use of diabetic medication when medical treatment of PBH was started
- Addison’s disease or glucocorticoid use
- pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2021
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-05-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9491
Other	RTPO Leeuwarden : RTPO nWMO 2021030

Study results