Prospective Observational Study Treating PBH In Daily Life

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20177

Source
Nationaal Trial Register

Brief title
POST-PBH-IDL

Health condition

post gastric bypass hypoglycemia

Sponsors and support

Primary sponsor: cnter obesity north netherlands / medical center leeuwarden
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

controle of hypoglycemic episodes leading to no interference in daily life

Secondary outcome

number of patients well controled on different medications

nember of patients with side effects on different medications

Study description

Background summary

Post bariatric hypoglycemia (PBH) is a frequently observed complication after bariatric surgery. The first treatment is a diet low in carbohydrates with frequent meals. a substantila number of patients will be well controled with diet alone, however there a more and more patients needing medical treatment. The medical treatment options for PBH are acarbose, diazoxide, somatostatin analogues and GLp-1 agonists. The literature on the results of these medications is limited to case reports and small cohort studies. There are currently no studies on treatment algorithms in larger cohorts. Internists involved with PBH in the Netherlands have agreed upon a treatment algorithm using stepwise acarbose, diazoxide, octreotide and finally liraglutide. The aim of this study is to prospectively document the percentage of success with the different medications using this algorithm. Patients can participate when they still have hypoglycemic complaints interfering with daily activities despite adequate dietary advice by a registered dietician with experience in post bariatric surgery patients. Data will be documented on patients charcteristics, surgery type, time to first hypoglycemic event, too of hypoglycemic documentation, frequency of hypos, quality of life (RAND36) and dumping severity (DSS).

Study objective

As there are no data on the percentage of success with the individual medications in the literature available a rough estimate based on personal experience is made.
50% will do well on acarbose
10% of the failures with acarbose will do well on diazoxide (0.1 x 0.5= 5%)
60% of failures on both will respond well to octreotide (0.6 x 45 = 27%)
leaving 100-50-5-27 = 18 % candidates for GLP-1 agonists
Starting with 100 patients information will be aquired with :
Acarbose : 100 pts
Diazoxide : 50 pts
Octreotide : 45 pts
GLP-1 analog : 18 pts

Study design

evaluation with each medication after 3 months

Intervention

none

Contacts

Public
Medisch Centrum Leeuwarden
Loek de Heide

0582866666
Scientific
Medisch Centrum Leeuwarden
Loek de Heide

0582866666

Eligibility criteria

Inclusion criteria

- either (Roux-en-Y gastric bypass) RYGB or OAGB (mini-gastric bypass)
- documented hypoglycemia with self measured glucose (SMBG) < 3.0 mM or blinded continuous glucose monitoring (cgm) 2.8 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

- current diabetes
- 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):	10-03-2020
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Not applicable

Application type:	Not applicable

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	NL8449
Other	RTPO Leeuwarden approved as non-WMO study : RTPO 1092

Study results