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

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none applicable

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON22335

**Bron**
NTR

**Verkorte titel**
PBH-MASTER

**Aandoening**

post bariatric hypoglycemia, RYGB, OAGB

### Ondersteuning

**Primaire sponsor:** Medical Center Leeuwarden
**Overige ondersteuning:** none

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

- 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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

none applicable

**Onderzoeksopzet**

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

**Onderzoeksproduct en/of interventie**

none

# Contactpersonen

## Publiek

Medisch Centrum Leeuwarden
Loek de Heide

0582866666

## Wetenschappelijk

Medisch Centrum Leeuwarden
Loek de Heide

0582866666

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- (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

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-06-2021 |
| Aantal proefpersonen: | 150 |
| Type: | Verwachte startdatum |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 19-05-2021 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL9491 |
| Ander register | RTPO Leeuwarden : RTPO nWMO 2021030 |

# Resultaten