Bariatric surgery in patients with craniopharyngioma

Gepubliceerd: 26-03-2021 Laatst bijgewerkt: 13-12-2022

We hypothesize that patients with craniopharyngioma and hypothalamic obesity have less efficacy of bariatric surgery compared to controls from a 'general' obese population

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22030

Bron
Nationaal Trial Register

Aandoening

Craniopharyngioma; (Hypothalamic) Obesity

Ondersteuning

Primaire sponsor: -
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

% Weight change

Toelichting onderzoek

Achtergrond van het onderzoek

Craniopharyngioma is a sellar tumour associated with high rates of pituitary deficiencies (~98%) and hypothalamic obesity (~50%). It is unknown whether long-term weight loss can be established with bariatric surgery in obese craniopharyngioma patients with hypothalamic dysfunction. Therefore, we perform a multicenter retrospective study where we compare weight loss after 1, 2, 3, 4 and 5 years in patients with hypothalamic obesity due to craniopharyngioma, with matched obese controls from the Scandinavian Obesity Surgery Registry, a nationwide registry. Controls have follow-up data available at 6 weeks, and 1, 2 and 5 years. Linear interpolation is performed for any missing values in patients or controls. The matching procedure is extensive: controls are selected according to gender, type of bariatric surgery (Roux-en-Y gastric bypass or sleeve gastrectomy), pre-operative T2DM, and pre-operative hypertension. Further matching is performed by year of obesity operation (10-year span category), age at obesity operation (10-year span category), and pre-operative body mass index (BMI) (maximum of ±5 kg/m2 different from the control). Controls are included only once. If less than 10 controls can be found, the matching terms are slightly broadened: the criterion for matching age at bariatric surgery is extended to ±10 years of the patient's age instead of a certain age category. In case of extreme BMI, the limt for BMI are not applied. Baseline statistics are compared between patients with obesity after craniopharyngioma and the matched controls from the SOReg database by Mann-Whitney U-test and Fisher's exact test for continuous and categorical data, respectively, and related continuous data are evaluated with Wilcoxon's rank test. Percentage weight change is then compared with a one-factor generalised randomised block design, with two-way analysis of variance applied with matched case-control units included as blocks. Blootstrapping is performed if this is needed to meet the assumptions of the test. Furthermore, the changes in pituitary replacement therapy are described.

Doel van het onderzoek

We hypothesize that patients with craniopharyngioma and hypothalamic obesity have less efficacy of bariatric surgery compared to controls from a 'general' obese population

Onderzoeksopzet

1, 2, 3, 4, 5 years follow-up

Onderzoeksproduct en/of interventie

Matched case control study: obese patients with craniopharyngioma and bariatric surgery are compared to obese controls with bariatric surgery and no history of craniopharyngioma

Contactpersonen

Publiek

Erasmus MC, Rotterdam, the Netherlands
Selvetta van Santen

+31650006438

Wetenschappelijk

Erasmus MC, Rotterdam, the Netherlands
Selvetta van Santen

+31650006438

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with craniopharyngioma who underwent bariatric surgery and have at least 2 years of follow-up

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	05-01-2020
Aantal proefpersonen:	16
Type:	Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL9374
Ander register	METC Erasmus MC : -

Resultaten

Samenvatting resultaten

-