Bariatric surgery in patients with craniopharyngioma

No registrations found.

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

Summary

ID

NL-OMON22030

Source
NTR

Health condition

Craniopharyngioma; (Hypothalamic) Obesity

Sponsors and support

Primary sponsor: -
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

% Weight change

Secondary outcome

Changes in pituitary replacement therapy

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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

Contacts

Public
Erasmus MC, Rotterdam, the Netherlands
Selvetta van Santen

+31650006438
Scientific
Erasmus MC, Rotterdam, the Netherlands
Selvetta van Santen

+31650006438

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

-

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	05-01-2020
Enrollment:	16
Type:	Unknown

IPD sharing statement

Plan to share IPD: No

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	NL9374
Other	METC Erasmus MC : -

Study results

Summary results

-