Influence of body weight on brain structure and function, the BARICO study, BAriatric surgery Rijnstate and RadboudUMC neuroImaging and Cognition in Obesity

Published: 30-04-2018
Last updated: 21-12-2024

To determine the effect of weight loss after bariatric surgery (BS) on different measures of cognition, brain function and structure investigated with various neuropsychological tests and studying various magnetic resonance imaging (MRI) parameters...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON55792

Source
ToetsingOnline

Brief title
The BARICO study

Condition

- Other condition
- Gastrointestinal therapeutic procedures

Synonym
Morbid obesity, overweight

Health condition

Morbide obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognition, Gastric Bypass, Neuroimaging, Obesity

Outcome measures

Primary outcome

We will assess the effect of bariatric surgery on cognitive performance on computerized neuropsychological tasks as well as brain functioning with MRI parameters, such as changes in cerebral blood flow (ASL) and structural and functional connections (DTI and fMRI).

Secondary outcome

Secundary study parameters are health status of the liver, adipose tissue and gut, change in microbiota, bloodplasma levels and lifestyle and dietary habits measured at different time-points to determine the relation with cognitive functioning.

Study description

Background summary

The prevalence of obesity is increasing and nowadays obesity-related diseases are one of the major health-care problems worldwide. There is a direct link between increased body mass and cognitive impairment. Body mass can be immediately decreased by rapid weight loss via bariatric surgery and this is associated with improved cognitive function. This may be due to changes in the interaction between metabolic organs and/or changes in the microbiota.

Cognitive benefit after bariatric surgery is not equally exhibited across patients and decline of cognitive improvements and increase in body weight after 24 months are as well reported. It has also not been possible to hypothesize about effects of bariatric surgery on the development of neurodegenerative diseases such as Alzheimer disease (AD) due to the relatively short length of follow-up and small numbers of bariatric surgery recipients in most of the studies reviewed. We therefore want to investigate mechanisms underlying obesity related disorders via longitudinal studies comprising neuroimaging and cognitive testing, aiming to elucidate whether the effects of bariatric surgery on blood, adipose tissue, gut and liver, and microbiota can attenuate adverse brain changes. Eventually, this study may lead to identification of mechanisms responsible for cognitive decline in obese individuals which will support the development of personalized treatments against obesity and prevention of AD.

Study objective

To determine the effect of weight loss after bariatric surgery (BS) on different measures of cognition, brain function and structure investigated with various neuropsychological tests and studying various magnetic resonance imaging (MRI) parameters. Secondary objectives are to determine health and inflammation status of adipose tissue, the liver and the gut, in relation to brain structure and function and whether BS affects gut microbiota composition and if these changes correlate with the neuropsychological functioning of the participants Furthermore, in a small study population we want to determine whether weight loss after bariatric surgery changes the inflammatory and atherogenic phenotype of innate immune cells. Eventually, this study may lead to identification of mechanisms responsible for cognitive decline in obese individuals which will support the development of personalized treatments against obesity and prevention of AD.

Study design

This study is an observational study, more specific a longitudinal study. The patients will be tested at different time-points using neuropsychological tests and analyses on several tissues, before and after Roux-en-Y Gastric Bypass Surgery (RYGBP). A subgroup of the participants will (next to the other parameters) be examined using MRI scanning .

Study burden and risks

The tissue biopsies, blood withdrawal and MRI measurements themselves do not pose any risk, if appropriate precautions are made.
The burden of participation for the subgroup of 75 patients consists of two visits to the Donders Institute in Nijmegen, undergoing a 45-minute MRI session in each. For all participants, biological samples will be collected during the

surgery. Therefore, the risks are considered to be minimal, considering the invasive nature of the surgery itself and the fact that the procedure is executed under complete anaesthetics. Participants will collect their faeces in a specially designed collection system that requires very little effort for the participants. Furthermore, the patients have to fill out some extra questionnaires and complete some neuropsychological tests next to the standard questionnaires. At last, maximal 43,5mL extra blood will be withdrawn at 8 time-point during regular blood withdrawal needed for the bariatric surgery. The patients do not have any additional visits to the hospital or the Dutch obesity center, all measurements (except MRI) will be performed during the regular visits and will take an estimated additional 2 hours in total of the patients* time. 5 and 10 years after surgery we contact the patients againto fill in the questionnaires and perform the cognitive tests once more. Furthermore we will again take some extra blood during regular blood withdrawal. Subjects participating in the study without MRI scanning will be reimbursed for with ¤90,-, when finishing the 2 year study procedure (patients in the MRI subgroup will receive ¤135,- and travel expenses).

Contacts

Public
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6800 TA
NL
Scientific
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6800 TA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Patients aged 35-55 years
- BMI > 40 kg/m2
- BMI > 35 and < 40 kg/m2 with co-morbidity, which is expected to improve after surgically-induced weight loss
- A history of longstanding obesity (> 5 years)
- Proven failed attempts to lose weight in a conventional way, or primarily successful weight loss with eventual weight regain
- Intention to adhere to a postoperative follow-up programme.

The only additional inclusion criterion for the MRI subgroup (75 patients) of this study includes:
- Patients must be willing to undergo MRI scanning and perform tasks in the MRI scanner, at the Donders Institute on three occasions. We include only right handed patients.

Exclusion criteria

- Previous or current neurological or severe psychiatric illness
- Pregnancy
- Past or current history of alcohol or drug abuse defined by criteria of the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV)
- Subjects who received any antibiotic, probiotic, or prebiotic agent three months before and during the start of the study.

Contra-indications to operative procedures as regular in bariatric surgery (according to Fried, Interdisciplinary guidelines)
- Psychiatric illness or mental instability, psychotic disorders, severe depression and personality disorders
- Absence of periods of identifiable medical management
- A patient who is unable to participate in prolonged medical follow-up
- Alcohol abuse and/or drug dependencies
- Diseases threatening life in the short-term or preoperatively
- Patients unable to care for themselves, and without long-term family or social support that will warrant such care

Contra-indications to MRI scanning:
- Claustrophobia
- Epilepsy
- Pacemakers and defibrillators
- Nerve stimulators

- Intracranial clips
- Intraorbital or intraocular metallic fragments
- Cochlear implants
- Ferromagnetic implants
- Lying circumference above > MRI space capacity

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	11-09-2018
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	30-04-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-08-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-06-2019
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-10-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-08-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-05-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28949
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63493.091.17
Other	NTR 29050