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How many patients have symptoms of early or late dumping after weight loss surgery and does these symptoms influence quality of life?

Submission date
07/10/2017

Recruitment status
No longer recruiting

Registration date
12/10/2017

Overall study status
Completed

Last Edited
10/08/2018

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Bariatric surgery is a weight loss surgery that reduces the size of their stomach. After weight loss surgery some patients develop complaints of dumping. Two forms of dumping exists: Early dumping, which starts early after a meal and resemble the complaints of a after dinner dip but then more heavily: symptoms of nausea, sleepiness, sweating, stomach ache etc. Late dumping mostly starts 1,5 hours after a meal and give complaints of hypoglycaemia (sweating, trembling, drowsiness or even coma). The aim of this study is to examine the prevalence of early and late dumping after bariatric surgery and examine the influence of this on patient's quality of life. The aim of this study is to examine the prevalence of early and late dumping after bariatric surgery and the impact of this on quality of life.

Who can participate?
Adults aged 18 and 70 years old who have underwent bariatric surgery.

What does the study involve?
Participants are asked to fill in one questionnaire some time after their bariatric surgery which takes 15 minutes. The questionnaire asks about late and early dumping and the impact on their quality of life.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participation.

Where is the study run from?
Medical Center Leeuwarden (Netherlands)

When is the study starting and how long is it expected to run for?
January 2012 to May 2013

Who is funding the study?
Center for Obesity Netherlands, Medical Center Leeuwarden (Netherlands)

Who is the main contact?
Mrs Marloes Emous
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
RTPO359a

Study information

Scientific Title
Prevalence of dumping after bariatric surgery and impact on quality of life

Study objectives
Research question:
What is the prevalence of early and late dumping after bariatric surgery and what is the influence on quality of life?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Examination Committee for Patient-Based Research, 05/23/2012, ref: number RTPO 859a

Study design
Single-centre cross-sectional study

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Post-bariatric population and dumping syndrome

Interventions
Participants are asked to fill in one questionnaire some time after their bariatric surgery which takes 15 minutes. The questionnaire asks about late and early dumping and the impact on their quality of life. No further actions are required.

Intervention Type
Other

Primary outcome(s)
Prevalence of late dumping is measured using the dumping severity score and questionnaire at one time point few years after bariatric surgery.

Key secondary outcome(s))
1. Prevalence of early dumping is measured using the dumping severity score and questionnaire at one time point few years after bariatric surgery
2. Impact on quality of life is measured using the dumping severity score and questionnaire at one time point few years after bariatric surgery

Completion date
01/05/2013

Eligibility

Key inclusion criteria
1. All patients who underwent bariatric surgery in a single hospital between 2008 and 2011
2. Aged between 18 and 70 years
3. All genders

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

There is no exclusion criteria.

Date of first enrolment
01/05/2012

Date of final enrolment
01/03/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
Medical Center Leeuwarden
Henri Dunantweg 2
Leeuwarden
Netherlands
8934 AD

Sponsor information

Organisation
RTPO

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Center for Obesity Netherlands, Medical Center Leeuwarden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Marloes Emous, surgeon and principal investigator at marloes.emous@znb.nl.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2017		Yes	No
Results article	results	01/08/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes