

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	☐ Prospectively registered ☐ Protocol
Registration date 12/10/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/08/2018	Condition category Surgery	☐ 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

Contact name

Mrs Marloes Emous

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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