

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

<b>Submission date</b> 07/10/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/10/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/08/2018	<b>Condition category</b> Surgery	<input type="checkbox"/> 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

marloes.emous@znb.nl

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Marloes Emous

### ORCID ID

<http://orcid.org/0000-0002-2223-3687>

### Contact details

Medisch Centrum Leeuwarden

Henri Dunantweg 2

Leeuwarden

Netherlands

8934AD

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**Secondary study design**

Cross sectional study

**Study setting(s)**

Hospital

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/01/2012

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

1250

**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

**Sponsor details**

Henri Dunantweg 2  
Leeuwarden  
Netherlands  
8934 AD

**Sponsor type**

Hospital/treatment centre

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Center for Obesity Netherlands, Medical Center Leeuwarden

**Results and Publications****Publication and dissemination plan**

1. One paper about the prevalence of early and late dumping after primary gastric bypass and their influence on quality of life
2. 1 paper about the prevalence of early and late dumping in patients after sleeve gastrectomy and revisional gastric bypass

**Intention to publish date**

01/11/2017

**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](mailto:marloes.emous@znb.nl).

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2017		Yes	No
<a href="#">Results article</a>	results	01/08/2018		Yes	No