24-hour urinary sodium and albumin excretion in the obese and the effects of bariatric surgery

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The objective of this study was to evaluate the effect of weight loss after bariatric surgery on blood pressure, renal parameters and renal function in obese patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON35938

Source
ToetsingOnline

Brief title
urinary sodium and albumin excretion in the obese

Condition

- Other condition
- Nephropathies

Synonym
nefropathy, renal insufficiency

Health condition

bariatrische chirurgie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: bariatric surgery, obesity, renal parameters

Outcome measures

Primary outcome

- prevalence of albuminuria in obese patients with and without co-morbidity

- mean natriuresis in obese patients and blood pressure

- relation between natriuresis and albuminuria

- the effect of weight loss on albuminuria, natriuresis, blood pressure,

medication

Secondary outcome

nvt

Study description

Background summary

Obesity and renal parameters
Obesity has acquired epidemic proportions in the United States, with nearly 65% of the adult population overweight and obese. In the Netherlands, the total percentage of overweight and obese people has increased from 44.1% of the population in 2000 (47.9% of all men and 40.4% of all women) to 47.2% of the population in 2009 (52.5% of all men and 41.9% of all women). 9.4% of the population belonged to the obese group in 2000 (8.6% of all men and 10.2% of all women) and this increased to 11.8% in 2009 (11.2% of all men and 12.4% of all women). This has led to an increase in the rate of bariatric procedures, with about 300 procedures performed in a year at the Slotervaart Hospital in Amsterdam, the Netherlands where the most common bariatric procedure is the Roux-en Y-gastric bypass.

Extreme obesity is associated with cardiovascular disease, type 2 diabetes, dyslipidemia, and hypertension. The steady increase in the prevalence of obesity contributes to the increase in the prevalence of chronic kidney disease, through renal damage associated with type-2 diabetes and hypertension. Obesity is an independent risk factor for the kidney, since it is associated with an increased risk of albuminuria and glomerulosclerosis, and worsens the course of chronic kidney disease regardless of the primary renal disease. The relationship between massive obesity and nephritic-range proteinuria was first reported in 1974. After that, increased evidence demonstrated that obesity-related glomerulopathy should be identified as an isolated complication of obesity.

Obesity is associated with glomerular hyperfiltration in animal models. Human studies also revealed abnormal renal haemodynamics in obese subjects, showing increased glomerular filtration rate, increased renal blood flow or both. Since one of the major determinants of proximal tubular reabsorption is the pressure gradient determined by Starling forces, the augmented oncotic pressure of the plasma entering the peritubular capillaries is expected to promote proximal tubular sodium reabsorption, salt retention and in increase in systemic arterial pressure.

Bariatric surgery produces greater weight loss and is more effective in controlling hypertension, diabetes, dyslipidemia, and other cardiovascular risk factors. However, its effect on renal parameters (e.g. changes in GFR, albuminuria, proteinuria and natriuresis) scarcely are described in the literature especially studies on the long-term evaluation of these effects after 2 years of follow-up. Therefore, the aim of this study was to evaluate the effect of weight loss on renal parameters in obese patients who have undergone bariatric surgery.

Study objective

The objective of this study was to evaluate the effect of weight loss after bariatric surgery on blood pressure, renal parameters and renal function in obese patients.

Study design

Observational study of patients who have undergone bariatric surgery in Slotervaart Hospital, Amsterdam, the Netherlands.

Study burden and risks

There are no risks expected for patients participating in this study.

Contacts

Public
Slotervaartziekenhuis

Louwesweg 6
1066 EC Amsterdam
NL
Scientific
Slotervaartziekenhuis

Louwesweg 6
1066 EC Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients (n=60) who have undergone bariatric surgery between December 2007 and February 2010 with a minimum follow-up time of 24 months.

Exclusion criteria

Patients whose 24-hour urinary samples before surgery are missing or incomplete will be excluded.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-06-2011
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	25-05-2011
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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
CCMO	NL36110.048.11