Postoperative effects of preoperative caloric and protein restriction.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28311

Source Nationaal Trial Register

Brief title PROTECT

Health condition

Live kidney donors - levende nierdonoren Bariatric surgery - bariatrische chirurgie Obesity-induced inflammation - Obesitas-geinduceerde inflammation Dietary restriction - Dieetrestrictie

Sponsors and support

Primary sponsor: - Rijksinstituut voor Volksgezondheid en Milieu (RIVM)
- Erasmus Medical Center
Source(s) of monetary or material Support: - Rijksinstituut voor Volksgezondheid en Milieu (RIVM)

Intervention

Outcome measures

Primary outcome

1. Safety and feasibility of a caloric and protein restricted diet measured by side-effects and metabolic parameters;

2. Induction of the protective stress response via a caloric and protein restricted diet, measured by markers of the stress response in tissue (biopsies) and blood.

Secondary outcome

1. Effect on subjective wellbeing and postoperative recovery after a caloric and protein restricted diet via questionnaires;

2. Acute phase response via blood samples.

Study description

Background summary

Animal studies over the past years have shown that caloric restriction (CR), the reduction of the amount of calories in our diet without causing malnutrition, has many positive effects like the extension of the lifespan. This response is collectively called the adaptive stress response. The precise etiology underlying this response is still unknown. One of the factors playing an important role is the better resistance against oxidative stress. Recently discovered is the role of protein restriction in this process. Previously to this research, a clinical study is performed in live healthy kidney donors given a diet of 3 days of 30% caloric restriction and 24 hours of fasting. This study showed the feasibility of such a diet in patients. With the present study, we first like to investigate the safety and feasibility of a caloric and protein restricted diet in a clinical setting. In the second phase we aim to study the mRNA and protein levels of markers of the adaptive stress response at a tissue level as well as the postoperative recovery.

Study objective

A protein and caloric restricted diet is feasible and safe and induces a protective stress response in patients undergoing live kidney nephrectomy or bariatric surgery.

Study design

Day -6, -1, +1, +2, +3, week 1, 2, month 1, 3, 6.

Intervention

1. A synthetic diet containing an estimate of 30% caloric restriction and 70% protein restriction that is based on the daily energy requirements;

2. Synthetic diet that is isocaloric to the daily energy requirements;

3. A control diet without any intervention with measurement of the nutritional intake via a dietary diary.

Contacts

Public

Dr. Molewaterplein 50 F. Jongbloed Rotterdam 3015 GE The Netherlands +31 (0)10 7043683

Scientific Dr. Molewaterplein 50 F. Jongbloed Rotterdam 3015 GE The Netherlands +31 (0)10 7043683

Eligibility criteria

Inclusion criteria

Group 1:

- 1. Live laparoscopic donor nephrectomy;
- 2. 18-55 years old;
- 3. BMI > 19.

Group 2:

- 1. Laparoscopic bariatric surgery;
- 2. 18-55 years old;
- 3. BMI > 40.

Exclusion criteria

Group 1: Allergic to the ingredients of the diet, bilateral abnormalities of the renal arteries, previous operations of the kidney(s) or adrenals gland(s), an open surgical approach.

Group 2: Allergic to the ingredients of the diet, other operations methods than the Roux-en-Y gastric bypass, previous operations of the stomach or duodenum, an open surgical approach, co-morbidity as in diabetes mellitus, morbid obesity caused by genetic defects/syndromes, another preoperative nutritional intervention necessary because of liver abnormalities.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

...

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-11-2012
Enrollment:	150
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	12-10-2012
Application type:	First submission

Study registrations

4 - Postoperative effects of preoperative caloric and protein restriction. 13-05-2025

Followed up by the following (possibly more current) registration

ID: 41323 Bron: ToetsingOnline Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3483
NTR-old	NTR3663
ССМО	NL39461.078.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41323

Study results

Summary results N/A