

Postoperative effects of preoperative caloric and protein restriction.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28311

Bron

Nationaal Trial Register

Verkorte titel

PROTECT

Aandoening

Live kidney donors - levende nierdonoren

Bariatric surgery - bariatrische chirurgie

Obesity-induced inflammation - Obesitas-geïnduceerde inflammatie

Dietary restriction - Dieetrestrictie

Ondersteuning

Primaire sponsor: - Rijksinstituut voor Volksgezondheid en Milieu (RIVM)

- Erasmus Medical Center

Overige ondersteuning: - Rijksinstituut voor Volksgezondheid en Milieu (RIVM)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-11-2012
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	12-10-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41323

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A