

A preoperative diet to increase resistance of patients undergoing surgery.

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Multiple studies have shown that dietary restriction extends lifespan in different animal species ranging from worms to rats. The beneficial effect of calorie restriction on life span may function in part through its ability to increase stress...

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

Samenvatting

ID

NL-OMON25155

Bron

Nationaal Trial Register

Verkorte titel

Dietary Restriction

Aandoening

Dietary restriction, Preoperative nutrition, Acute phase response, Surgery

Preoperative voeding, Dieet, Acute fase reactie, operatie

Ondersteuning

Primaire sponsor: Prof. J.N.M IJzermans

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Postoperative course of CRP, IL-6, IL-8 and IL-10.

This is an pilot study and therefore no sample size calculation is performed.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

Multiple studies have shown that dietary restriction extends lifespan in different animal species ranging from worms to rats. The beneficial effect of calorie restriction on life span may function in part through its ability to increase stress resistance. We hypothesize that the mechanisms involved in extended longevity may also be tapped for short-term clinical benefits against acute stress such as the acute phase response after surgery.

Onderzoeksopzet

Preoperatively and at days 1,2,3 and 4 the donors blood samples will be collected and analyzed.

Preoperatively and at 1,3,6 and 12 months postoperatively donors are asked to complete forms related to the quality of life and the ability to perform daily tasks and (if applicable) the time of regaining working activities.

Onderzoeksproduct en/of interventie

Based on reported calorie intake patients randomized to the dietary restriction group start a 30% calorie restricted diet three days pre-operatively. The day before surgery the donor is allowed to have a light breakfast followed by 12 hours of fasting. Until midnight preoperatively they are allowed to drink water ad libitum.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Scheduled for laparoscopic donor nephrectomy;
2. 18 years ≤ age ≤ 80 years;
3. BMI ≤ 18.5.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

If inclusion criteria are not met.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	11-09-2007
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	24-06-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1765

Register

NTR-old

Ander register

ISRCTN

ID

NTR1875

METC Erasmus MC : METC-2007-1999

ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A