

A preoperative diet to increase resistance of patients undergoing surgery.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25155

Source

Nationaal Trial Register

Brief title

Dietary Restriction

Health condition

Dietary restriction, Preoperative nutrition, Acute phase response, Surgery

Preoperative voeding, Dieet, Acute fase reactie, operatie

Sponsors and support

Primary sponsor: Prof. J.N.M IJzermans

Erasmus MC

Dr. Molewaterplein 50

3015 Ge Rotterdam

010-7043683

Source(s) of monetary or material Support: This research was funded by a stimulation grant (05040202, Healthy Ageing) from the Netherlands Genomics Initiative (NGI)/Netherlands Organisation for Scientific Research (NWO). And by grants from Lifespan-EC-LSHG-CT-2007-036894, NIH-AG0171242 and Ride-Zon MW-948-00-019.

Intervention

Outcome measures

Primary outcome

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

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

Secondary outcome

Preoperatively and at days 1,2,3,7 and 14 the donors score pain and nausea on a visual analogue scale from 0 (none) to 10 (severe) and report the ability to perform daily tasks in the euroQoL questionnaire.

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.

Study description

Background summary

N/A

Study objective

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.

Study design

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.

Intervention

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.

Contacts

Public

Erasmus University Medical Center

PO Box 2040
J.N.M. IJzermans
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7033727

Scientific

Erasmus University Medical Center

PO Box 2040
J.N.M. IJzermans
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7033727

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

If inclusion criteria are not met.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	11-09-2007
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion	
Date:	24-06-2009
Application type:	First submission

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
NTR-new	NL1765
NTR-old	NTR1875
Other	METC Erasmus MC : METC-2007-1999
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A