Ischemic damage control in live kidney donation

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31315

Source
ToetsingOnline

Brief title
EnergyReduction

Condition

- Other condition

Synonym
healthy donors

Health condition

gezonde nierdonoren

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Netherlands Genomics Initiative via NWO

Intervention

Keyword: Energy reduction, Live kidney donation

Outcome measures

Primary outcome

Recovery of the patient postoperative.

Secondary outcome

interleukines, TNF, LDH and high-sensitive CRP, quality of life and fatigue,

cytokine response

Study description

Background summary

Organ transplantation is the only long-term curative treatment for patients with chronic kidney failure. mplementation of live donation ensures transplantation of a non-diseased organ before the kidney disease progresses to it*s terminal fase requiring dialysis. This provides a better transplant function in the acceptor. The Erasmus Medical Centre has one of the biggest live kidney donating programmes in the Neteherlands. In this programme healthy volunteers donate their kidney to another person. The post operative recovery is very important in these healthy volunteers. Using "nutritional pre-conditioning", by reducing the preoperative intake, we aim to improve the post operative recovery.

Study objective

1. The objective of this pilot study is to investigate if 72 hours 30% calorie restriction + 24 hours of pre-operative fasting has a beneficial effect on post-operative recovery. 2. The perioperative cytokine response in fasting and non-fasting patients undergoing donor nephrectomy will be investigated.3. The changes in the insulin/ IGF-1 (somatotroph) pathway will be determined. 4. Patients VAS,MFI-20, SF-36, EuroQol and work related scores are documented at

regular times to measure postoperative recovery.5. Transcriptional changes índicative of inflammation in per-operative biopsies of donated kidneys will be compared between both groups.

Study design

The experimental group will record their nutrition intake during 2 random week days and one weekend day according to a dietary form. Based on reported calorie intake patients start a 30% calorie restricted diet three days preoperatively.
The day before surgery the donor is allowed to have a light breakfast followed by 24 hours of fasting. Until midnight preoperatively they are allowed to drink water ad libitum.
There is no restriction on the diet of the control group during the preoperative days. They will also fill in the dietary forms.These patients are fasted overnight as usual.
Transcriptional changes índicative of inflammation in per-operative biopsies, obtained through standard procedures, of donated kidneys will be compared between both groups
Serum creatinine, ureum, glucose, insulin, IGF-1, interleukins, TNF, LDH and high-sensitive CRP are measured at pre-arranged times: 12 hours preoperatively, 6 hours postoperatively, and daily until discharge.
At three weeks, three months, six months and one year postoperatively donors are asked to complete forms related to pain, nausea, fatigue, and quality of life. Preoperatively and at days 1, 3, 7, and 14 the donors score pain and nausea on a visual analogue scale from 0 (none) to 10 (severe).
To assess whether preoperative energy restriction differentially affects health related quality of life and fatigue, we use the SF-36 and the multidimensional fatigue inventory 20 (MFI-20) preoperatively and at 1, 3, 6 months and 1 year postoperatively.

Intervention

72 hours of dietary restriction followed by 12 extra hours of fasting pre-operatively during which water is allowed ad libitum. (total 24 hours of fasting)

Study burden and risks

dietary form
energy reduction
postoperative forms at regular times

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

live kidney donors

Exclusion criteria

- Bilateral abnormalities of the renal arteries (origin stenosis)
- Previous operations of the kidney or adrenal gland
- Radiological abnormalities necessitating an open approach
- Peroperative conversion to an open approach.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-08-2007
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	14-08-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL18177.078.07