Fasting before live kidney donation, effect on donor wellbeing and postoperative recovery

No registrations found.

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

Summary

ID

NL-OMON22140

Source
Nationaal Trial Register

Brief title
FAST-Study

Health condition

Live kidney donation, postoperative recovery, ischemia-reperfusion injury

Sponsors and support

Primary sponsor: Investigator Initiated
Source(s) of monetary or material Support: Investigator Initiatied

Intervention

Outcome measures

Primary outcome

Postoperative fatigue, scored by 36-Item Short Form Health Survey (RAND-36). The primary endpoint will be measured 4 weeks after surgery.

Secondary outcome

Our secondary endpoints comprise several aspects of the preoperative fasting diet, postoperative recovery and ischemia-reperfusion-injury: postoperative fatigue, admission time, adherence to the fasting diet, physical activity, renal function of the donor and recipient, upregulation of cytoprotective genes and anti-inflammatory markers, the use of uEV as a diagnostic approach and the immune-modulating effect of fasting.

Study description

Background summary

Rationale: Enhanced Recovery After Surgery (ERAS) reduces both hospital stay and complication rates. Part of the ERAS protocol consists of early postoperative mobilization and ad libitum diet. No clear recommendation of a preoperative diet has been made. Further research should be conducted to improve the recovery time and lessen postoperative fatigue, one of the main postoperative effectors on donor quality of life (QoL). Caloric restriction (CR) is associated with extended life span, lower risk of age associated diseases, improved fitness and increased resistance to acute stress. CR represents a non-invasive, non-expensive method of mitigating the effects of acute surgery-induced stress. Short-term CR increases expression of cytoprotective genes, increases immunomodulation via increased anti-inflammatory cytokine production and also decreases the expression of pro-inflammatory markers. Live kidney donors are an excellent population to further investigate the potential beneficial effect of DR. To investigate whether the beneficial effect of preoperative fasting reduces the postoperative fatigue after live kidney donation, a large randomized clinical trial is needed. This research is needed since postoperative fatigue is one of the main effectors on donor quality of life.

Objective: to determine whether nutritional preconditioning by 2,5 days of fasting reduces postoperative fatigue score, 4 weeks after live kidney donation.

Study design: multicenter randomized controlled trial

Study population: patients and donors opting for living kidney donation and transplantation at Erasmus University Medical Center in Rotterdam and University Medical Center Groningen.

Intervention: a control group receiving current standard of care and an intervention group fasting for 2,5 days with a low dose laxative for 3 days.

Main study parameters/endpoints: Postoperative fatigue, 4 weeks after live kidney donation. Secondary endpoints include f.i. effect of preoperative fasting on postoperative hospital admission time, the feasibility of the fasting diet & adherence to the fasting diet, renal function of the donor and the transplanted patient, the use of urinary extracellular vesicles in renal transplantation and the immune-modulating effect of fasting.

Study objective

We aim to investigate whether a preoperative fasting diet reduced postoperative fatigue at 4 weeks after living donor nephrectomy in adult patients

Study design

12 weeks and 3 days before surgery and 3 days, 4 and 12 weeks after surgery

Intervention

Subjects in the intervention group will start a preoperative fasting regime from 60 hours before surgery. Fasting is defined as very few to no caloric intake. Subjects are free to drink unlimited water, tea and coffee to maintain a sufficient fluid balance. In addition, they are allowed a daily dose of 100 grams of vegetables (cucumber, baby carrots and baby tomatoes). To prevent the loss of electrolytes they are allowed 4 bouillons a day. After surgery, they can resume their usual diet at own discretion. During the fasting period, subjects will use 1 dose of Macrogol 3350 daily, to reduce a common side-effect of fasting: constipation. Macrogol will be used the same way it has been approved for and used in daily practice.

Contacts

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Eligibility criteria

Inclusion criteria

Adult patients and donors opting for living kidney donation and transplantation at: Erasmus MC, University Medical Center in Rotterdam, The Netherlands and University Medical Center Groningen in Groningen, The Netherlands

In order to be eligible to participate in this study, a subject going for live kidney donation must meet all of the following criteria:
- Age between 18 and 70 years old
- BMI between 19 and 35 kg/m2
- Able to provide written consent
- Adequate understanding of the Dutch language

Exclusion criteria

A potential subject (Donor) who meets any of the following criteria will be excluded from participation in this study:
- Participants of the cross-over kidney donation program
- Participation in another prospective trial/study for living kidney donors
- HLA- or bloodtype-incompatible living kidney donation

A potential subject (Recipient) who meets any of the following criteria will be excluded from participation in this study:
- the use of double anticoagulants (f.i. Ascal (Carbasalate Calcium) and Clopidogrel (Plavix)).
- the need for therapeutic anticoagulation with low-molecular weight heparine during admission for kidney transplantation, also known as “Bridging”.

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):	01-03-2021
Enrollment:	180
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-02-2021
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	NL9262
Other	METC-Erasmus MC : MEC-2020-0777

Study results