

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

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

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

Samenvatting

ID

NL-OMON22140

Bron

Nationaal Trial Register

Verkorte titel

FAST-Study

Aandoening

Live kidney donation, postoperative recovery, ischemia-reperfusion injury

Ondersteuning

Primaire sponsor: Investigator Initiated

Overige ondersteuning: Investigator Initiated

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Postoperative fatigue, scored by 36-Item Short Form Health Survey (RAND-36). The primary

endpoint will be measured 4 weeks after surgery.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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".

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 24-02-2021

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	NL9262
Ander register	METC-Erasmus MC : MEC-2020-0777

Resultaten