

Dietary INtervention effect on the recovery after kidney dOnation

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We are interested to see whether a sulforaphane enriched diet will improve post-operative recovery in healthy patients who donate a kidney for the purpose of a kidney transplantation.

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

Summary

ID

NL-OMON47180

Source

ToetsingOnline

Brief title

DINO-trial

Condition

- Other condition
- Renal and urinary tract therapeutic procedures

Synonym

Broccoli diet vs. postoperative oxidative stress

Health condition

dieet interventies

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W, Mkb-innovatiestimulering Regio en Topsectoren (MIT) in samenwerking met Koppert Cress Bv, Monster, Topsectorbeleid; MKB innovatie stimulering; overheid; MIT samenwerkingsproject

Intervention

Keyword: broccoli, postoperative, stress response, sulforaphane

Outcome measures

Primary outcome

Primary:

- Serum: leukocytes, crp and pro-inflammatory cytokines (IL-6, TNF-a, IFN-g, IL-10)

Secondary outcome

Secondary:

- Serum: sICAM, sVCM
- Biopsies: oxidative stress markers (Ho-1, SOD, GST)
- Questionnaires (VAS, euroqol, SF-36, MFI-20, werk en zorg)

Study description

Background summary

This research deals with the physical stress of surgery and recovery thereafter. Previous research has shown that broccoli contains sulforaphane. This substance is a well-known antioxidant and appears to reduce the level of oxidative stress. Oxidative stress occurs in situations that could be harmful to the body such as heat, UV light and smoking. This oxidative stress also occurs during surgery. With this study we would like to assess whether a broccoli enriched diet provides better resistance to oxidative stress and thus to the outcome of the operation. Patients who are going to donate their kidney for the purpose of transplantation (healthy) will be included in this study. 40

patients will be included and will be asked to consume standardized foodboxes the five days before surgery. The foodboxes have no sulforaphane containing products. In the intervention group (n=20) an additional sulforaphane rich (broccoli cress shake) is added. Patients will have to visit the outpatient department one extra time before surgery for a vena puncture and to hear which group they are randomized to. During surgery, after removal of the kidney, 3 biopsies will be taken. During admittance an additional blood tube will be collected during the standard blood withdrawal. Furthermore, participants will receive questionnaires about quality of life, pain, nausea and well-being (VAS EuroQol SF-36, MFI 20, work and care) preoperatively, during hospitalization, 1 week, 2 weeks and 3 months after surgery. The serum will be tested on leukocytes, CRP, pro-inflammatory cytokines (IL-6, TNF- α , IFN- γ , IL-10), intercellular cell adhesion molecules (ICAM), and vascular cell adhesion molecule (VCAM). The biopsies will be examined for markers of oxidative stress (HO-1, SOD, GST).

Study objective

We are interested to see whether a sulforaphane enriched diet will improve post-operative recovery in healthy patients who donate a kidney for the purpose of a kidney transplantation.

Study design

This is a pilot study in which 50 healthy patients will be included who are listed to donate a kidney for the purpose of a kidney transplantation.

- 25 patients will receive standardized foodboxes with an additional sulforaphane enriched shake (broccoli sprouts)

- 25 patients will only receive the standardized foodboxes

The foodboxes are the same in both groups and will not contain product with sulforaphane.

Intervention

Standardized food boxes with or without an additional sulforaphane enriched broccoli sprouts shake.

Study burden and risks

Participant will undergo:

- 1 additional outpatient department visit including one extra vein puncture (30min)

- 5 days preoperatively a standardized diet with or without the broccoli sprouts diet

- Daily after surgery one extra tube of blood, besides the standard blood

withdrawal

- 3 kidney biopsies, after the kidney is removed from the participant
- Questionnaires: pre-operatively, daily for during admittance and 1 week, 2 weeks and 3 months after surgery. Filling out these questionnaire will take about 10min

We expect no risks of this diet

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

Healthy people who are listed to donate a kidney for the purpose of kidney transplantation

Exclusion criteria

- Age <18 years
- Standard use of corticosteroid or non-steroidal anti-inflammatory drugs (NSAIDs) medication that might influence inflammatory response
- multiple arteries of the kidney that will be donated (kidney recipients will then receive heparin postoperative, which increases the risk on post-operative bleeding from the biopsy sides)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	18-01-2016
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO	
Date:	18-11-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	02-05-2018
Application type:	Amendment
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	NL53890.078.15