Evaluation of intrarenal oxygenation in patients after receiving a kidney from non-heart-beating and living donors by BOLD MRI on a 3.0 T scanner 1 day after surgery.

Published: 09-03-2009
Last updated: 06-05-2024

The current study is designed to test the hypothesis that the medulla in transplanted kidneys is still hypoxic at 1 day after transplantation using a non-invasive method: BOLD MRI.By studying two groups a comparison can be made between patients...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON33999

Source
ToetsingOnline

Brief title
Intrarenal oxygenation in kidney transplantation

Condition

- Other condition
- Nephropathies
- Renal and urinary tract therapeutic procedures

Synonym
ischemia/reperfusion injury, kidney transplantation

Health condition

Transplantatie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Kidney transplantation, Medullary oxygenation, Reperfusion injury

Outcome measures

Primary outcome

Hypoxia

1. Medullary and cortical oxygenation (R2*)

Secondary outcome

Hypoxia

1. Medullary and cortical O2 consumption (after furosemide administration)

2. Medullary and cortical perfusion (after Gadovist administration)

3. Urine HIF-1a and carbonic anhydrase IX concentration

Kidney function

1. Dialysis dependency after transplantation

2. Area under the curve for serum creatinine concentration over time (14 days)

3. Fractional excretion of sodium (14 days)

Renal cellular injury

1. Examining biopsies according to protocol

Study description

Background summary

Renal blood flow, a quarter of the cardiac output and the highest in the body in relation to organ weight, is directed mostly to the cortex to optimize glomerular filtration rate and the reabsorption of solute. In the physiologic situation, blood flow to the hairpin loops of the renal medulla, in contrast, is low, to preserve osmotic gradients and enhance urinary concentration. The medullary partial pressure of oxygen is in the range of 10 to 20 mm Hg, contrasting with the partial oxygen pressure of approximately 50 mmHg in the cortex. Medullary hypoxia may have important implications in renal failure after transplantation which is associated with variable periods of ischemia.

Animal studies strengthen the view that ischemic insults leads primarily to disturbance of the medullary perfusion [5, 6]. We have observed similar results in our ischemia/reperfusion mouse model in which we find a highly hypoxic medulla in de ischemic injured kidney in contrast to the contra lateral kidney until 24 hours after reperfusion (E.E. de Vries, M.G.J. Snoeijs, W.H. Backes, unpublished observations). It can be concluded that the outer medulla is particularly vulnerable for ischemic/reperfusion injury and this ongoing hypoxia and impaired perfusion could lead to ischemic organ failure in humans.

Study objective

The current study is designed to test the hypothesis that the medulla in transplanted kidneys is still hypoxic at 1 day after transplantation using a non-invasive method: BOLD MRI.
By studying two groups a comparison can be made between patients after transplantation of kidneys with various degrees of ischemia. This information may improve the rational selection of interventional strategies to attenuate renal ischemia/reperfusion injury and to improve post-operative kidney function. Furthermore, it may provide a new diagnostic tool for application in future clinical trials or setting in acute ischemic renal failure and kidney transplantation.

Study design

Observational study

Study burden and risks

One day postoperatively patients will get an extra MRI examination. Through a peripheral venous line (standard care) furosemide is administered, after which a small amount of Gadovist will be administered. Old versions of this contrast agent bear a small risk of a serious skin disorder (NSF), however this new agent Gadovist has no reported cases of NSF so far. Urine can be taken from the katheter already in situ.
After 3 months this procedure will be repeated. Because of the absence of a peripheral venous line, we will have to apply one. We will ask patients to collect some (50 mL) urine.

Contacts

Public
Academisch Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
Nederland
Scientific
Academisch Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients receiving a kidney from a living donor

Patients reveiving a kidney from a NHB donor
Living donors
Donor age > 18 years
Able to give informed consent
Written informed consent

Exclusion criteria

Age < 18 years
Donor > 60 years

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	36
Type:	Anticipated

Ethics review

Not approved

Date:	09-03-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL24422.068.08