Circulation and Hemodynamics in Living Donor Kidney Transplantation in Children

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Adequate perfusion of an adult-sized renal graft in children demands significant hemodynamic changes after transplantation (Tx). Suboptimal renal graft perfusion due to inadequate hemodynamic adaptation increases the risk of loss of renal graft mass...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nephropathies
Study type	Observational non invasive

Summary

ID

NL-OMON22098

Source
Nationaal Trial Register

Brief title
CHILD-KiTC

Condition

- Nephropathies

Health condition

renal failure pediatric living donor kidney transplantation cardiac output renal perfusion

Research involving
Human

Sponsors and support

Primary sponsor: Radboud university medical center
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

absolute values and changes of CO and flow in aorta, a. renalis donor kidney

qualitative perfusion of donorkidney

biomarker concentration in blood and urine

pharmacon and metabolite concentration in blood

Secondary outcome

-patient characteristics recipient: sex, age, weight, length, renal disease, co-morbidities, medical history, medication

-laboratory results, e.g. renal function

-hemodynamic parameters (blood pressure, heart rate) during the study period

-fluid administration

-medication (inotropes and antihypertensive drugs)

-surgical and anesthetic record of the kidney transplantation

-diuresis

-number of hospital admissions first year postKT plus cause of admission

-ICU and hospital stay after KT

-renal graft ischaemic times (cold and warm)

-patient and graft survival

-postoperative complications KT

Study description

Background summary

single center, pilot study in children with kidney transplantation of living donor (LDKT) to investigate hemodynamic and circulation changes, kidney specific biomarker profiles and pharmacokinetic differences after KT.

Study objective

Adequate perfusion of an adult-sized renal graft in children demands significant hemodynamic changes after transplantation (Tx). Suboptimal renal graft perfusion due to inadequate hemodynamic adaptation increases the risk of loss of renal graft mass and function. This risk is especially large in the smaller and younger recipients. Current monitoring of renal graft perfusion in the post transplantation period is insufficient to detect early deterioration in blood supply. Goal of this study is to develop a non-invasive, bed-side monitor for renal perfusion after pediatric kidney transplantation. Moreover, pharmacokinetic changes after adult sized kidney transplantation in young children are largely unknown As signiflcant changes are expected, caused by increased renal and possibly hepatic blood flow, this study will investigate the pharmacokinetic (Pk) model of several pharmacons in this specific patient group.

Study design

acceptor:

pre-transplantation: MRI and ultrasound (US) kidney/aorta, cardiac US, CO measurement , blood and urine sampling.

post transplantation: MRI and US kidney, cardiac US, CO measurement, blood and urine sampling.

1,3, 12 months post transplantation:

US kidney, blood and urine sampling

6 mo postTx echo cor, MRI and US kidney, blood and urine sampling

donor: MRI and US kidney. DNA analysis

Intervention

cardiac ultrasound

MRI

ultrasound donor kidney

blood and urine sampling

cardiac output monitoring

Contacts

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Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (12-15 years)
Adolescents (16-17 years)
Adolescents (16-17 years)
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

Recipients:

1)Age between 0-15 years.

2) Scheduled for living donor kidney transplantation.

3) Signed informed consent by recipient and/or parents.

4) Bodyweight maximum 40 kg

Donors:

1)Accepted as kidney donor for the pediatric recipient by the responsible doctors.

2) Signed informed consent

Parents:

1) Biological parent of the donor kidney recipient

2) Signed informed consent

Exclusion criteria

Exclusion criteria for participation of the recipients are complex congenital cardiac diseases (hemodynamic significant intracardiac shunts, cyanotic cardiac disease) and refusal of consent. Subjects with a contra-indication for MRI can be enrolled in the study to participate in all other investigations (biomarker en Pk profile, cardiac output analysis).

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-11-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	06-11-2017
Application type:	First submission
Review commission:	METC Oost-Nederland

Study registrations

Followed up by the following (possibly more current) registration

ID: 45477
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6666
NTR-old	NTR6900
CCMO	NL61392.091.17
OMON	NL-OMON45477

Study results