Circulation and Hemodynamics in Living Donation of Kidney Transplantation in Children

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal and urinary tract disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON45477

Source
ToetsingOnline

Brief title
CHILD KiTC

Condition

- Renal and urinary tract disorders congenital
- Nephropathies

Synonym
donor kidney perfusion

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac output monitoring, pediatric kidney transplantation, pharmacokinetics, renal graft perfusion

Outcome measures

Primary outcome

1)Absolute values and percentage change in CO, AoBF and transplanted renal

artery blood flow (TxRBF) after adult-sized kidney transplantation in pediatric

recipients.

2) urine and serum biomarker concentrations.

3) pharmacon and metabolite serum concentrations.

(see page 15 research protocol)

Secondary outcome

see page 16 research protocol

Study description

Background summary

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 significant 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 objective

Primary objective is to design a non-invasive, bedside monitoring strategy for early detection of renal graft hypoperfusion after pediatric kidney transplantation, using transabdominal ultrasonography and biomarker surveillance in serum and urine.
Secondary objective is to define a pharmacokinetic (Pk) model for adult sized kidney transplantation in children.

Study design

This is a prospective clinical pilot study.

Study burden and risks

The extra burden for the participants consists of blood sampling, additional MRI and ultrasound investigations in addition to standard of care in pediatric kidney transplantation. In small children this implies an extra anesthesia session for the performance of the last MRI. Extra blood samples will be drawn as part of regular blood sampling in standard of care and will not exceed the maximum allowable amounts.
Benefits are especially accounted for the future pediatric kidney transplant patients. Though, imaging the renal graft during follow up can also benefit the study subjects as it is able to detect early deterioration in renal graft blood supply and perfusion. This study can only be done in this patient group as hemodynamic changes are age and body-weight specific and especially the smallest recipients are at risk for inadequate renal graft perfusion because of large allograft-recipient size mismatch. Adult data about hemodynamic responses, renal graft perfusion and pharmacokinetic changes cannot be extrapolated to the pediatric population.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

recipients (children; 20 persons):
1) Age between 0-17 years, bodyweight < 40 kg
2) Scheduled for living donor kidney transplantation.
3) Signed informed consent by child and/or parents. ;Donors (adults;20 persons):
1)Accepted as kidney donor for the pediatric recipient by the treating doctors.
2) Signed informed consent;Parents (2 per recipient/child)
1) signed informed consent

Exclusion criteria

complex congenital heart disease in the acceptor (child) and refusal of informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-11-2017
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	06-11-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-12-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22098
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL61392.091.17
OMON	NL-OMON22098