Remote Ischemic Conditioning in Renal Transplantation - Effect on Immediate and Extended Kidney Graft Function

Published: 08-08-2013
Last updated: 24-04-2024

Investigate wether rIC, a simple, non-invasive procedure which could be easily implemented in clinical care, can improve immediate and long term kidney graft function after transplantation from deceased donors

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

Summary

ID

NL-OMON40158

Source
ToetsingOnline

Brief title
context study

Condition

- Other condition

Synonym
Kidney Graft Function, Renal Transplantation

Health condition

niertransplantatie

Research involving
Human

Sponsors and support

Primary sponsor: anesthesiologie- onderzoeksbureau
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Kidney Graft Function, Remote Ischemic Conditioning, Renal Transplantation

Outcome measures

Primary outcome

he initial rate of plasma creatinine decline and the need for dialysis post transplantation constitute the primary endpoint (DGF). The method for describing the rate of creatinine decline has been established in corporation with a statistician and is based on data from earlier transplanted patients

Secondary outcome

Additional endpoints include:

1) GFR measured from 24 hours urine collection at day 5 post transplantation as well as 3 and 12 months after transplantation measured from Ioodthalamaat clearance according to standard institutional guidelines,

2) urinary and plasma biomarkers of acute kidney injury,

3) rejection episodes.

Furthermore, we planned to investigate possible mechanisms of ischemia/reperfusion injury and potential, protective effects of rIC by analysing important mediators in renal biopsies, plasma and urine.

Study description

Background summary

About 25% of renal transplantations from deceased donors are complicated by delayed graft function (DGF). DGF increases the risk of rejection and shortens graft survival, thus implying heavy costs to the affected individuals as well as on society.

DGF is caused by ischemia and reperfusion injury (IR-injury) of the renal tissue. Remote ischemic conditioning (rIC) is a technique where repetitive, short term ischemia is induced in one tissue, e.g. an arm or a leg, leading to systemic protection against ischemia elsewhere in the body. Clinical studies have shown, that rIC following acute myocardial infarction and before revascularisation, reduces the myocardial damage. The Aarhus group has used rIC in a porcine kidney transplantation model involving brain dead donors and showed that rIC improved renal graft perfusion and glomerular filtration rate (GFR).

The purpose of the CONTEXT study is to investigate whether rIC can improve immediate and long term renal graft function after transplantation from deceased donors.
The initial rate of decline in plasma creatinine and the need for dialysis post transplantation, delayed graft function (DGF) constitute the primary endpoint . The method for describing the rate of creatinine decline has been established in corporation with a statistician and is based on data from earlier transplanted patients. The goal is a rate of decline of 30% more in the rIC group, a goal considered clinically relevant. With a power of 0.8 a total of 200 patients are needed.

Study objective

Investigate wether rIC, a simple, non-invasive procedure which could be easily implemented in clinical care, can improve immediate and long term kidney graft function after transplantation from deceased donors

Study design

investigator initiated, randomised double-blinded, interventional study

Intervention

rIC is performed on the opposite thigh of graft placement by four cycles of 5 min ischemia induced by a tourniquet inflated to 250 mmHg. Each cycle is separated by 5 min of free blood flow. The sham procedure consists of a pressure of 20 mmHg blocked by a pean on the tube connecting to the tourniquet.

Study burden and risks

The tourniquet placed on the contrallateral leg in order to induce the rIC is

used in other circumstances, mainly at orthopedic operations, and it is designed to create bloodless field by inflating it to 250-300 mmHg. With a prolonged usage over 1-2 hours with constant ischemia, light skin damages can occur if the skin was folded under a wrongly applied tourniquet. In the rIC protocol the tourniquet is inflated to 250 mmHG for 5 minutes and than deflated for 5 minutes. This cycle will be repeated four times. No risks are assessed for the patient by rIC, since the procedure is short and interrupted by free flow of blood.
The rIC intervention is not associated with any discomfort for the patient who is anaesthetised during the procedure.
Two routine biopsy*s during the procedure are taken according to standard institutional guidelines and are a routine procedure during kidney transplantation in our hospital. A piece of this material will be used for analysis. . A biopsy has a small risk of bleeding, as do all biopsies. When so occur it will be sutured by the surgeon according to standard institutional guidelines. Taking of biopsies do not have negative consequences on kidney function
Blood and urine samples at the ward are taken together with standard samples whenever possible, and are not expected to give further risks or discomfort.
The extra blood samples during operation are taken from the arterial line placed in the arteria radialis according to standard institutional guidelines.
The total volume of bloodsamples taken is 134 ml. Urine samples are taken from the catheter bag and are non invasive.
GFR measurement at 3 months and one year followup are standard of care

Contacts

Public
Selecteer

hanzeplein 1
groningen 9713 EZ
NL
Scientific
Selecteer

hanzeplein 1
groningen 9713 EZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

•Age 18 and above
•Received information, signed consent
•Candidate for kidney transplantation from deceased donor

Exclusion criteria

•Can't give informed consent
•AV-fistula in the leg opposite the site where the graft will be placed
•Threatening ischemia in the leg

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2013

Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	08-08-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-01-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT01395719
CCMO	NL44320.042.13