Repeated IPC
ischemic preconditioning, RIPC, ischemic reperfusion injury, endothelial function, end-stage renal disease, flow-mediated dilation (FMD)

ischemisch preconditioneren (IPC), herhaalde IPC, ischemisch reperfusie schade, endotheel functie, flow-gemedieerde dilatatie

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29689

Source
NTR

Health condition

To examine the effect of daily repeated ischemic preconditioning on brachial artery endothelial function (measured as FMD% before and after IRI) during 7 days in patients with chronic kidney disease.

We will recruit 20 subjects with chronic kidney disease. The presence of a patent arterio-venous fistula (for dialysis) and peripheral artery occlusive disease (stage Fontaine 3-4) are

taken as exclusion criteria. Also patients with pathology of both arms (for example, sclerodermia, dystrophy, recent trauma, chronic wounds) will be excluded.

Sponsors and support

Primary sponsor: Radboudumc Nijmegen
Source(s) of monetary or material Support: Afdeling Chirugie, UMC St Radboud Telefoon: 024-3615333

Intervention

Outcome measures

Primary outcome

Brachial artery endothelial function (measured as flow-mediated dilation)

Secondary outcome

To examine the effect of daily repeated ischemic preconditioning arm on superficial femoral artery function (measured as FMD%) during 7 days in patients with chronic kidney disease.

To examine the effect of daily repeated ischemic preconditioning on ex vivo innate immune responses

Study description

Background summary

To examine the effect of daily repeated ischemic preconditioning on brachial artery endothelial function (measured as FMD%) during 7 days in patients with chronic kidney disease.

Explorative, single-center study

20 patients with chronic kidney disease stage 4-5.

Remote RIPC: 4 cycles of ischemia of the forearm by inflating a blood pressure cuff around the upper arm at 200 mmHg during 5 minutes followed by 5 minutes of reperfusion

Main study parameters/endpoints: Brachial artery endothelial function (measured as flow-mediated dilation).

Study objective

In this explorative study we will examine the impact of daily ischemic preconditioning on brachial artery endothelial function (measured as FMD%, before and after IRI) during 7 days in the non-shunt arm and lower limb in patients with end-stage renal disease. Also the effects of repeated RIPC on ex vivo innate immune responses will be explored as well. Our primary hypothesis is that RIPC can improve brachial artery FMD% in patients with end-stage renal disease.

Study design

screening 2 weeks in advance

informed consent 1 week in advance

testing day 1

week later testing day 2, start intervention 7 days RIPC

week later testing day 3, final visit

Intervention

Remote RIPC: 4 cycles of ischemia of the forearm by inflating a blood pressure cuff around the upper arm at 200 mmHg during 5 minutes followed by 5 minutes of reperfusion. This procedure will be performed daily during 7 days.

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Eligibility criteria

Inclusion criteria

Informed consent

Age > 18 years

Patients with chronic kidney disease (CKD stage 4 or 5)

Exclusion criteria

-The presence of a patent arterio-venous fistula (for dialysis)

-Peripheral artery occlusive disease stage III and IV. Poor peripheral skin vascular can interfere with performance of superficial femoral artery measurements

-Simultaneous participation in another interventional study

-Impossibility to perform RIPC, due to pathology of both arms (for example, sclerodermia, dystrophy, recent trauma, chronic wounds)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-02-2015
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-01-2015
Application type:	First submission

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
NTR-new	NL4949
NTR-old	NTR5054
Other	CMO regio Arnhem-Nijmegen : 2014-1344

Study results