

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29689

Bron

NTR

Aandoening

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.

Ondersteuning

Primaire sponsor: Radboudumc Nijmegen

Overige ondersteuning: Afdeling Chirurgie, UMC St Radboud

Telefoon: 024-3615333

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Informed consent

Age > 18 years

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	04-02-2015
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	30-01-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4949
NTR-old	NTR5054
Ander register	CMO regio Arnhem-Nijmegen : 2014-1344

Resultaten