

# THE EFFECT OF REPEATED REMOTE ISCHEMIC PRECONDITIONING ON ENDOTHELIAL FUNCTION AND INNATE IMMUNE RESPONSES IN PATIENTS WITH END-STAGE RENAL DISEASE

Published: 15-12-2014

Last updated: 21-04-2024

Examine the impact of 7-day daily ischemic preconditioning on brachial artery endothelial function (measured as FMD%) in the dominant arm (i.e. local effect: primary objective) and contra-lateral arm (i.e. remote effect: secondary objective) in...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON40693

### Source

ToetsingOnline

### Brief title

repeated IPC

### Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

### Synonym

kidney disease patients with dialysis

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** dialysis, endothelial function, ischemic preconditioning

## Outcome measures

### Primary outcome

The change in endothelial function after a 7-day intervention (measured as the brachial artery flow-mediated dilation for the primary objective and contra-lateral brachialartery flow-mediated dilation for the secondary objective).

### Secondary outcome

brachial artery endothelial function in the dominant arm after ischemia-reperfusion injury

## Study description

### Background summary

The endothelium, i.e. the inner layer of arteries, plays a crucial role in maintaining vascular integrity and health. Patients with kidney disease undergoing dialysis demonstrate endothelial dysfunction and it is reported that brachial artery endothelial function measured as the flow-mediated dilation (FMD%) has predictive capacity for prognosis. Therefore, improving FMD% seems to have clinical relevance.

Ischemic preconditioning (IPC) refers to the exposure of tissue to short, repeated bouts of ischemia. Whilst IPC has protective effects against prolonged ischemia, we and other recently found the potential of repeated, daily IPC to improve endothelial function in healthy volunteers. To date, no previous study examined the potential of repeated, daily IPC to improve endothelial function in subjects with a priori endothelial dysfunction, such as in subjects with

kidney disease. Furthermore, it is unknown whether repeated, daily IPC can improve endothelial function in the arm exposed to the IPC-stimulus as well as distant vascular beds (i.e. remote effect).

## **Study objective**

Examine the impact of 7-day daily ischemic preconditioning on brachial artery endothelial function (measured as FMD%) in the dominant arm (i.e. local effect: primary objective) and contra-lateral arm (i.e. remote effect: secondary objective) in subjects with kidney disease

## **Study design**

Explorative study

## **Intervention**

7 day, daily, unilateral IPC (4X5-minutes of occlusion of the upper arm using a blood pressure cuff)

## **Study burden and risks**

Measures (FMD and endothelium-independent dilation) and interventions (repeated IPC) are not associated with any potential health risk. Even in this group of kidney disease patients undergoing dialysis, we expect no potential health risk of our measures and interventions.

## **Contacts**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

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

### Exclusion criteria

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

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-01-2016

Enrollment:	20
Type:	Actual

## Ethics review

Approved WMO	
Date:	15-12-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	05-01-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	03-03-2015
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

No registrations found.

### In other registers

Register	ID
CCMO	NL49583.091.14