

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

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	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