A randomized clinical trial to assess the effect of repeated remote ischaemic postconditioning on infarct size in patients with an ischaemic stroke

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To examine the impact of remote ischaemic postconditioning after an ischaemic stroke on infarct size and clinical outcome in patients, but also to better understand the potential underlying mechanisms contributing to these effects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON46558

Source
ToetsingOnline

Brief title
Repeated RIPostC

Condition

- Central nervous system vascular disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
cerebral vascular accident, Ischaemic stroke

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Clinical outcome, Infarct size, Ischaemic conditioning, Stroke

Outcome measures

Primary outcome

Difference in final infarct size between the intervention and control group.

Infarct size will be measured using MRI.

Secondary outcome

The primary outcome (infarct size) will be linked to our secondary outcomes:

Clinical outcome and vascular, immune, and anti-inflammatory pathways.

Study description

Background summary

Past decades, advances in pharmacological and endovascular treatment have markedly improved outcome in patients with an ischaemic stroke. Nevertheless, the therapeutic window to target, reduce and/or attenuate the detrimental impact of ischaemic brain injury is limited (i.e. 6-hr after stroke), with no subsequent treatment options available. This highlights the need for innovative treatment options, which preferably extend beyond the first 6-hr post-stroke to further attenuate brain damage. A possible solution to this problem is remote ischaemic postconditoning (RIPostC), which is an application of brief non-lethal periods of ischemia and reperfusion to activate innate responses that leads to protection against prolonged periods of ischemia. This intervention consists of inflation of a blood pressure cuff around the upper arm. Recent research shows compelling evidence is present regarding the benefits of repeated exposure to remote ischaemic conditioning after an ischaemic event.

Study objective

To examine the impact of remote ischaemic postconditioning after an ischaemic stroke on infarct size and clinical outcome in patients, but also to better understand the potential underlying mechanisms contributing to these effects.

Study design

Randomized double blind clinical trial

Intervention

Remote RIPostC: 4 cycles of ischaemia of the arm by inflating a simple blood pressure cuff around the upper arm at 20 mmHg above systolic blood pressure during 5 minutes followed by 5 minutes of reperfusion. This will be performed twice a day during the complete duration of hospitalization.

Study burden and risks

All techniques that will be applied in this study have been used several years by the Department of Physiology and Neurology, some even longer than 15 years. None of the procedures described above are *new* and all procedures are an integrated part of several previous studies that have been accepted by the ethics committee. To our best knowledge, none of the techniques applied in this study have been associated with adverse effects. We believe that the risks of the testing procedures of this study are minimal, while the subjects will be monitored closely throughout the study.

Contacts

Public
Radboud Universitair Medisch Centrum

Reinier postlaan 4
Nijmegen 6525 GC
NL
Scientific
Radboud Universitair Medisch Centrum

Reinier postlaan 4
Nijmegen 6525 GC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Informed consent
Age >18 years
Clinically diagnosed ischaemic stroke using the WHO definition for stroke

Exclusion criteria

Unstable vital signs
Admitted >24 hours after onset of symptoms
Upper extremity injury or edema contra-indicating RIPostC.
Mastectomy on both sides

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-04-2018
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	14-12-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-04-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-06-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-12-2019
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	NL62753.091.17