# The effect of repeated remote ischaemic postconditioning on infarct size in stroke patients.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON21188

**Source**
NTR

**Brief title**
REPOST

**Health condition**

Stroke, CVA, herseninfarct

### Sponsors and support

**Primary sponsor:** Radboudumc, Nijmegen
**Source(s) of monetary or material Support:** Radboudumc, Nijmegen

### Intervention

### Outcome measures

**Primary outcome**

To examine the impact of repeated daily remote ischaemic postconditioning, starting on the day of an ischaemic stroke on infarct size after 4 days or at the end of hospitalization (using MRI).

### Secondary outcome

Explore the effect of repeated daily remote ischaemic postconditioning on clinical outcome after 12 weeks (using the modified ranking score; degree of disability/dependence).

Assess the impact of repeated daily remote ischaemic postconditioning on validated and frequently used markers of vascular, immune, and anti-inflammatory pathways, and relate these effects to total infarct size and clinical outcome.

## Study description

### Background summary

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 single blind placebo-controlled clinical trial

Study population: 200 patients with ischaemic stroke who are being admitted to the emergency room of the Radboudumc.

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.

Main study parameters/endpoints: Difference in final infarct size between the intervention and control group. Infarct size will be measured using MRI. This primary outcome will be linked to our secondary outcomes: Clinical outcome and vascular, immune, and anti-inflammatory pathways.

### Study objective

The hypothesis is that repeated remote ischaemic postconditioning (by improving vascular, immune and anti-inflammatory pathways) will minimize infarct size and, subsequently, will improve clinical outcome in stroke patients.

**Study design**

Day of stroke: Baseline measurements for markers of vasculari, immune and anti-inflammatory pathways. informed consent.

Day1-4: Intervention twice daily.

Four days past stroke or at the end of hospitalization: Infarct size, blood sampling, clinical outcome in acute setting (NIHSS)

Twelve weeks: Clinical outcome (modified ranking score), Quality of life (SS-QoL)

Twelve months: Clinical outcome (modified ranking score), hospitalization, morbidity and mortality.

**Intervention**

Repeated remote ischaemic postconditioning (RIPostC): 4 cycles of ischaemia of the arm by inflating a blood pressure cuff around the upper arm at 20 mmHg above systolic blood pressure during 5 minutes followed by 5 minutes of reperfusion. This procedure will be performed twice a day (morning and afternoon) during the complete duration of hospitalization after the ischaemic stroke. The intervention will be administered by a trained researcher.

# Contacts

**Public**
T.R.J. Landman
Nijmegen
The Netherlands
024-3614087
**Scientific**

T.R.J. Landman
Nijmegen
The Netherlands
024-3614087

# Eligibility criteria

## Inclusion criteria

- Informed consent

- Age >18 years

- Clinically diagnosed ischaemic stroke using the WHO definition for stroke (“Stroke was defined as a rapidly evolving focal neurological deficit, without positive phenomena such as twitches, jerks or myoclonus, with no other than a vascular cause”).

## Exclusion criteria

Unstable vital signs

Admitted >24 hours after onset of symptoms

Upper extremity injury or edema contra-indicating remote ischaemic conditioning

Mastectomy on both sides

MRI contra-indications

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Placebo |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-02-2018 |
| Enrollment: | 200 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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|---|---|
| Date: | 08-12-2017 |
| 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 | NL6710 |
| NTR-old | NTR6880 |
| Other | CMO regio Arnhem-Nijmegen : 2017-3711 |

## Study results