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

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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.

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

Samenvatting

ID

NL-OMON21188

Bron
NTR

Verkorte titel
REPOST

Aandoening

Stroke, CVA, herseninfarct

Ondersteuning

Primaire sponsor: Radboudumc, Nijmegen
Overige ondersteuning: Radboudumc, Nijmegen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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”).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2018
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-12-2017
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	NL6710
NTR-old	NTR6880
Ander register	CMO regio Arnhem-Nijmegen : 2017-3711

Resultaten