

The effect of ischemic preconditioning in patients with cerebral small vessel disease

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We hypothesize that both remote ischemic conditioning and exercise conditioning activate the release of circulating blood factors. We expect that the repeated application shows higher levels of these circulating blood factors

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26118

Bron

NTR

Verkorte titel

CONDITIONED

Aandoening

Cerebral small vessel disease

Ondersteuning

Primaire sponsor: Radboudumc

Overige ondersteuning: Radboudumc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The difference in circulating blood factors (related to vascular immune and anti-inflammatory pathways) between baseline and after four days of intervention (RIC/EC).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: There is no proven effective treatment to attenuate the progression of cerebral small vessel disease (cSVD), leading to long-term disability and mortality in patients who suffer from this disease. A new innovative treatment option could be related to preconditioning. There are several methods to apply preconditioning, including Remote ischemic conditioning (RIC) and exercise conditioning (EC). Although preconditioning represents a low-cost non-invasive treatment strategy to potentially attenuate the progression of cerebral small vessel disease, little work examined the potential distinct physiological responses between single versus repeated preconditioning. Secondly, although both ischemic and exercise conditioning may have clinical benefit, little work explored whether both types of preconditioning elicit a comparable physiological response.

Objective: To explore the effect of single versus repeated preconditioning on circulating blood factors (i.e. metabolomics analysis) as a likely mechanism in patients with cSVD. Secondly, we explore whether the effects of single versus repeated preconditioning differs between ischemic and exercise conditioning on circulating blood factors of patients with cSVD.

Doel van het onderzoek

We hypothesize that both remote ischemic conditioning and exercise conditioning activate the release of circulating blood factors. We expect that the repeated application shows higher levels of these circulating blood factors

Onderzoeksopzet

Cross-over 2x one week (with one week of wash-out in between). Every week we have three time points:

- Baseline
- 1 hour after a single bout of ischemic conditioning
- After 4 days of repeated ischemic conditioning

Onderzoeksproduct en/of interventie

Remote ischemic conditioning: inflation of a small cuff around the upper arm at 200 mmHg or 20 mmHg above systolic blood pressure: 4x5 min with 5 minutes of reperfusion. This procedure will be performed twice a day (morning and afternoon) for 4 days.

Exercise conditioning (EC): 4x5 min of handgrip exercise, followed by 5 minutes rest. Twice daily for four days. This exercise will be performed twice a day (morning and afternoon) for 4

days.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Informed consent
- Age >60 years
- Diagnosed cerebral small vessel disease (all of the participants in de RUNDMC study have confirmed cSVD on MRI imaging)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Upper extremity injury or edema contra-indicating RIC or EC.
- Mastectomy on both sides

Onderzoekopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	04-10-2020
Aantal proefpersonen:	16
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	24-09-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49220
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8911
CCMO	NL74436.091.20
OMON	NL-OMON49220

Resultaten