Remote ischemic preconditioning and pain

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Pain is an unpleasant experience with a multifactorial aetiology. It is feared by most people undergoing surgery. In the postoperative period pain is controlled using many different drugs. All of these drugs have their own adverse events. Ideally…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23701

Bron
Nationaal Trial Register

Aandoening

Remote ischemic preconditioning
Pain
QST (Quantitative Sensory Testing)

Geisoleerde ischemische behandeling
Pijn
QST (kwantitatieve sensorische testen)

Ondersteuning

Primaire sponsor: drs. V.D. Linssen
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Overige ondersteuning: eerste geldstroom (Geld van Ministerie van OC&W aan universiteiten)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Does ischemic preconditioning alters pain perception in healthy individuals measured with QST?

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Pain is an unpleasant experience with a multifactorial aetiology. It is feared by most people undergoing surgery. In the postoperative period pain is controlled using many different drugs. All of these drugs have their own adverse events. Ideally pain is controlled by a non-invasive method whereby no adverse events occur. A possible non-invasive method to reduce pain is remote ischaemic preconditioning (RIPC). Current practice could change on a large scale if the link between RIPC and lower pain scores can be confirmed. If we are able to demonstrate this, in future less analgesics will be needed. Complications and adverse events of analgesics can be overcome that way.

Objective of the study:

The effect of 10 minutes of ischemic preconditioning produced with a pneumatic tourniquet on pain perception.

Study design:

An observational study of a double session per subject; QST will be measured before application of the pneumatic tourniquet and after 10 minutes of pneumatic tourniquet pressure

Study population:

Healthy human volunteers, 18-65 years old

Primary study parameters/outcome of the study:
Does ischemic preconditioning alters pain perception in healthy individuals measured with QST?

Secundary study parameters/outcome of the study (if applicable):

• Has ischemic preconditioning a different effect on pressure pain thresholds and electrical pain thresholds measured with pressure pain thresholds (PPT), electrical pain detection threshold test (EPT) and cold pain thresholds (CPT)?

• How painful are 10 minutes of ischemic preconditioning using a pneumatic tourniquet 50 mmHg above volunteers SBP measured with VAS?

• Is there a correlation between the score of an individual on the Pain Catastrophe Scale and pain thresholds?

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):

Participation involves two sessions of at most six hours, including Quantitative Sensory Testing, Depression Anxiety Stress Scales and Pain Catastrophe Scale, as well as application of 10 minutes of pneumatic tourniquet pressure 50 mmHg above the volunteers systolic blood pressure. The anticipated risks for the study subjects are well defined and of short duration. Therefore, participation in this study does not represent an undue risk for subjects.

Doel van het onderzoek

Pain is an unpleasant experience with a multifactorial aetiology. It is feared by most people undergoing surgery. In the postoperative period pain is controlled using many different drugs. All of these drugs have their own adverse events. Ideally pain is controlled by a non-invasive method whereby no adverse events occur. A possible non-invasive method to reduce pain is remote ischaemic preconditioning (RIPC). Current practice could change on a large scale if the link between RIPC and lower pain scores can be confirmed. If we are able to demonstrate this, in future less analgesics will be needed. Complications and adverse events of analgesics can be overcome that way.

Onderzoeksopzet

QST measurements containt:

- Cold pain thresholds will be measured using the ice water bucket.

- Pressure Pain Thresholds (PPT) are tested by use of a pressure algometer. PPT is measured on the left and right body side once at the thenar (middle part).

- Electric pain thresholds (EPT) are tested by use of the QST-3 device (JNI Biomedical ApS,

Klarup, Denmark) on the left and right body side. Measurement location is the musculus rectus femoris (20 cm above patella).

The Pain Catastophe Scale (PCS) can be completed and scored in less than 5 minutes. The PCS instructions ask participants to reflect on past painful experiences, and to indicate the degree to which they experienced each of 13 thought or feelings when experiencing pain, on 5-point scales with the end points (0) not at all and (4) all the time.

Volunteers are asked to fill in a standardized questionnaire for depression and anxiety. The questionnaire used is the DASS - Depression Anxiety Stress Scales

Onderzoeksproduct en/of interventie

An observational study of a double session per subject; QST will be measured before application of the pneumatic tourniquet and after 10 minutes of pneumatic tourniquet pressure. In one session the tourniquet will be inflated 50 mmHg above volunteers systolic blood pressure. In the other session the tourniquet will be inflated at 20 mmHg. The sequence of the sessions will be randomized with drawing envelopes.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Healthy

18 – 65 years old

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Cognitive malfunction

• Not being able to abstain from analgesics 1 day before examination or taking analgesics regularly

• Body mass index (BMI) of > 35 kg/m2

• Post-traumatic lengthy hand reconstruction on both upper extremities

• Severe crushing injuries on both upper extremities

• Skin grafts on both upper extremities

• Pregnancy or nursing

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	Niet-gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	02-06-2014
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-06-2014
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	NL4507
NTR-old	NTR4625
CCMO	NL47776.091.14

Resultaten