Remote ischemic preconditioning and pain

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23701

Source
Nationaal Trial Register

Health condition

Remote ischemic preconditioning
Pain
QST (Quantitative Sensory Testing)

Geisoleerde ischemische behandeling
Pijn
QST (kwantitatieve sensorische testen)

Sponsors and support

Primary sponsor: drs. V.D. Linssen
Universitair Medisch Centrum Radboudumc
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Source(s) of monetary or material Support: eerste geldstroom (Geld van Ministerie van

OC&W aan universiteiten)

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

• 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?

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

Healthy

18 – 65 years old

Exclusion criteria

• 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-06-2014
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

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

Study results