CIVS

No registrations found.

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

Summary

ID

NL-OMON20823

Source
NTR

Brief title
CIVS

Health condition

Healthy individuals

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: Leiden University Medical Center (LUMC)

Intervention

Outcome measures

Primary outcome

The main study outcome is the difference in CPM between the ‘standard’ protocol and the ‘home’ protocol.

Secondary outcome

Several questionnaires

Study description

Background summary

Rationale: Conditioned Pain Modulation (CPM) protocols differ across research sites all over the world. Data regarding the influence of the variation in protocols on the CPM outcome is lacking. To explore the factors that contribute to CPM variability we will conduct several CPM protocols in healthy volunteers in different laboratories over the world. The study will include two protocols, a standard protocol common to all participating laboratories, and a second protocol, the 'home protocol' used on each site. Each site will compare their own protocol to the standard protocol. Furthermore, all data will be transferred to the Rambam University in Israel for a overall analysis to explore factors that contribute to CPM variability.
Objective: To explore the factors that contribute to CPM variability in order to optimize testing protocols and minimize variability.
Study design: Observational study
Study population: 40 healthy volunteers
Intervention (if applicable): NA
Main study parameters/endpoints: The primary outcome is the difference in measured CPM between the standard and the home protocol.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden for the patients is the time consumption while visiting our research facility. The CPM testing can induce short term effects e.g. skin redness or mild pain. Measuring CPM does not produce longer lasting effects.

Study objective

We hypothesize there is a difference in CPM between the protocols

Study design

Subjects will visit our facility on one occasion

Intervention

Standard CPM protocol vs LUMC CPM protocol

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy according to medical history, physical examination and vital signs;
2. Age 18-40;
3. Able to give informed consent;

Exclusion criteria

1. Presence of health issues including clinical pain of any kind in the previous 3 months;
2. Any use of pain medication;
3. Pregnancy or lactation;
4. Participation in another study at the same time;
5. Presence of in dept knowledge or experience of/in CPM testing or CPM study methods
6. Presence of Raynaud phenomenon;

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	11-01-2021
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	07-01-2021
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	NL9175
Other	METC LDD : P20.084

Study results