CPM inter-site variability study (CIVS)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49156

Source
ToetsingOnline

Brief title
CIVS

Condition

- Other condition

Synonym
endogenous pain modulation

Health condition

geen aandoening, onderzoek naar endogene pijnstilling

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Conditioned pain modulation, intersite, variability

Outcome measures

Primary outcome

Explore the factors that contribute to CPM variability in order to optimize

testing protocols and minimize variability

Secondary outcome

na

Study description

Background summary

Conditioned pain modulation (CPM) is an experimental test to evaluate the endogenous pain modulatory system. It consists of a painful test stimulus (mostly heat pain on the lower arm) and a conditioning stimulus on a remote area which is able to facilitate or inhibit the pain of the test stimulus.

CPM protocols differ across research sites all over the world which makes comparison between studies hard. Data regarding the influence of the variation in protocols on CPM outcome is lacking.

Study objective

To explore the factors that contribute to CPM variability we will conduct various CPM protocols in healthy volunteers. The study will include two protocols, a standard protocol common to all sites, and a second protocol, the *home protocol* used at each specific site.

Next, all data will be collected from the various sites. Data from the standard protocol will be used to analyze variation between sites, and it*s possible contributing factors. The second protocol will serve to identify the influence of specific deviations from the standard protocol (e.g. testing modalities, body sites etc.), and develop correction factors for these parameters that will allow comparison of results from the various protocols used. The LUMC will only perform the CPM tests, the statistical analysis will be performed elsewhere.

Study design

The study is an experimental validation study to explore factors that contribute to CPM variability in order to optimize testing protocols and minimize variability. The subjects in the study will attend one session in which two CPM protocols will be tested. The standard protocol will be performed randomized to the 'home protocol'. Between the two, a break of 30 minutes is incorporated. The total protocol will take about 3 hours to complete. The study will be performed in the anesthesiology research facility

Intervention

CPM tests - a method to quantify endogenous pain modulation

Study burden and risks

Study duration is 3 hours, in which the volunteers will receive several pain tests. These tests are safe and can induce shortlasting itch or redness of the tested skin. There are negligible risks. The burden is limited; it is a single visit.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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

Exclusion criteria

-Presence of health issues including clinical pain of any kind in the previous 3 months;
-Use of continuous pain medication;
-Pregnancy or lactation;
-Participation in another study at the same time;
-Presence of in dept knowledge or experience of/in CPM testing or CPM study methods

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2021
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	24-12-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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
CCMO	NL74710.058.20