Pain sensitivity in children with chronic pain and their mothers

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The objectives of this study are:1) assess the differences in pain sensitivity between children with and without chronic pain2) collecting normative data for pain sensitivity in children aged 8-123) investigate the relationship between parental...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON32919

Source
ToetsingOnline

Brief title
Pain sensitivity in children

Condition

- Other condition

Synonym
chronic pain; pain complaints

Health condition

chronische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Erasmus Fonds Pijnbestrijding

Intervention

Keyword: children, chronic pain, mothers, pain sensitivity

Outcome measures

Primary outcome

Difference in pain sensitivity between children with and without chronic pain

Difference in pain sensitivity with and without the mothers' presence

Secondary outcome

not applicable

Study description

Background summary

The relationship between chronic pain in children and sensitivity to pain is influenced by the way the mother deals with her childs' pain. Until now, pain sensitivity in children with chronic pain has mainly been studied in children recruited from tertiary health care clinics. Not all children with chronic pain are referred to a hospital and chronic pain in the community is very common; 19% of children aged 4-7 and 23% of children aged 8-11.

Study objective

The objectives of this study are:
1) assess the differences in pain sensitivity between children with and without chronic pain
2) collecting normative data for pain sensitivity in children aged 8-12
3) investigate the relationship between parental factors, such as parenting behavior and pain coping of the mother, and child pain sensitivity
4) investigate the relationship between the mothers' pain sensitivity and the pain sensitivity of her child

Study design

Experimental study

Study burden and risks

Before testing the mother will be shown a short instruction video.

TSA
Thermal detection and pain thresholds will be measured in children and mothers. All thermal stimuli will be induced with the Medoc Thermal Sensory Analyzer (TSA) II. This is a precise, computer-controlled device capable of generating and recording response to a highly repeatable thermal stimulus. A contact thermode (30x30mm) will be used to apply cold or heat. The entire thermode-stimulating surface will be placed in contact with the skin-testing site. The minimum temperature is
-10°C and the maximum is 50°C. Starting from a baseline temperature of 32°C warmth and cold the temperature will change at 1°C per second (warmer or colder).
Before the thermal test is performed the subjects are instructed to press the button when a cold sensation is first perceived. After this the thermode returns to the baseline temperature of 32°C. This is repeated five times to calculate the cold sensation detection threshold. The same procedure is carried out for the warm sensation detection threshold. For detection of the cold 'pain' and heat 'pain' thresholds, subjects are instructed not to press the button when they feel the warm or cold sensation but to press the button when the cold or warm sensation gets painful. After they press the button the thermode returns to the baseline temperature. If the subject does not press the button before -10°C or 50°C the test will automatically terminate, returning to the baseline temperature.

The published studies to date did not report any problems regarding the use of the thermal test in children and children's willingness to participate is good (Meier et al., 2001).

Neurometer
The detection and pain thresholds will be measured through electrical stimulation, with the neurometer (Neurotron, Incorporated). This device is capable of measuring the three different fibers (C fibers, A-delta fiber and A-beta fibers). Because the neurometer can stimulate the different fibers separately, we also want to use this. Different studies show that the different methods to measure pain thresholds, show different results, although inconsistently (Janal et al., 1994; Lautenbacher et al., 1994; Neddermeyer et al., 2008).
With different frequencies (2000Hz, 250Hz, 5Hz) applied with a gold-plated electrode with a 1cm diameter, the different fibers will be stimulated. The measures will not be influenced by skin thickness, temperature or edema. Before the beginning of the test the subjects will receive instructions. The electrode

will be coated with an electroconductive and taped to the skin. The stimulus for the different frequencies will range from 0 to 9.99mA en will increase as long as the subject presses a button. For the detection threshold the subject will receive the instruction to release the button as soon as he or she feels something. As soon as the button is released, the stimulus is stopped. For the pain threshold the subject is instructed not to release the button as soon as he feels anything, but when it becomes painful. With this button the subjects will have full control over when they want to stop the test.

Experimental situation
The pain tolerance will not be measured, therefore the pain experienced will be limited. To determine the influence of the mother's detection and pain threshold, both tests will first be administered to the mother. The children will do both tests twice, once in the mother's presence and once without. One half will start with the mother present and the other half will start without the mother.

Mothers and children will also fill out some questionnaires

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

no chronic pain or any other disease (for healthy group of children)
chronic pain, without a somatic cause. In the Pain questionnaire the following question adresses this: 'Has a doctor assess a cause of the pain?'
children aged 8-12 years

Exclusion criteria

Dutch language skills not sufficient to fill out the questionaires and understand the instructions

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL
Recruitment status:	Pending
Start date (anticipated):	01-09-2008

Enrollment:	350
Type:	Anticipated

Ethics review

Approved WMO Date:	18-11-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL24327.078.08