Quantitative Sensory Testing in Juvenile Idiopathic Arthritis

Published: 10-01-2014
Last updated: 24-04-2024

Primary Objectives: 1.1: To evaluate the feasibility of determining sensory thresholds in patients with JIA using QST.1.2: To examine which sensory modalities are particularly affected in JIA patients compared to healthy controls in order to define...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON40592

Source
ToetsingOnline

Brief title
QST in JIA

Condition

- Autoimmune disorders

Synonym
Juvenile idiopathic arthritis, juvenile rheumatoid arthritis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: JIA, pain, QST

Outcome measures

Primary outcome

Pain sensitivity levels of the QST battery: Pain thresholds for temperature

(hot,cold), pinprick, pressure, temporal summation of pinprick (*wind-up*), and

allodynia.

Secondary outcome

Detection sensitivity levels of the QST battery: temperature (warm, cold),

mechanical, and vibration.

Study description

Background summary

Juvenile idiopathic arthritis (JIA) is a common childhood rheumatic disease potentially resulting in long-term disability persisting into adulthood in more than one-third of the patients. Acute pain is a clinically significant symptom of JIA, with pain persisting in approximately 40% of JIA patients for months to years. This pain is hard to treat
Identification of those patients at risk of developing chronic pain is needed to be able to start early treatment aimed at preventing the transition from acute to chronic pain.
A cornerstone of investigating both acute and chronic pain in JIA patients is the measurement of pain. Recently a valid and reliable methodology has been developed that can objectively and accurately assess pain: quantitative sensory testing (QST). In adult populations, this methodology has been used extensively and has proven to produce intra-individually repeatable and internationally comparable data. A validated standardized quantitative sensory testing (QST) protocol has been developed which can reliably be used in healthy children over 5 years. It is currently unknown if QST testing is also feasible in JIA patients and no reference data exist..

Study objective

Primary Objectives:
1.1: To evaluate the feasibility of determining sensory thresholds in patients with JIA using QST.
1.2: To examine which sensory modalities are particularly affected in JIA patients compared to healthy controls in order to define an optimal set of QST-tests in future studies.
Secondary Objectives:
To evaluate the role of age, sex, JIA subtype and medication use in QST findings.

Study design

This is a monocenter observational cross-sectional, case-control study.

Study burden and risks

Benefits:
Patients with JIA often suffer from (severe) pain. Being able to reliably measure pain in this group makes it possible to better study the mechanisms driving pain, particularly the transition from acute to chronic pain. A better understanding of these mechanisms can lead to new treatments to decrease pain in patients with JIA.

Risk assessment:
The potential risks are negligible and the burden of study participation is minimal. Sensory tests are all protocolized and considered safe, with no risk for serious injuries. No tissue will be damaged, since the measurement devices are designed to operate within margins that will not cause tissue damage. The level of discomfort is minimal, since the measurements stop the moment the subject notices the sensation to become painful. The pain tests described in this protocol have been used for research previously.

Group relatedness:
JIA is a disorder which presents itself in childhood with a severe risk of continuing in adulthood. The participation of children with JIA is mandatory to gain more knowledge of pain mechanisms in this syndrome.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Healthy controls will be matched to JIA patients based on age and sex.
In order to be eligible to participate in this study, a patient must meet all of the following criteria:
- From 6 to 17 years of age
- Ability to speak Dutch
-Be diagnosed with active JIA by their treating physician as defined by the ILAR-classification and patient reported pain rating greater than 10 (on a 0-100mm scale).
- The most severe inflammation must be in the knee;Healthy controls must meet all of the following criteria:
- From 6 to 17 years of age
- Ability to speak Dutch

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
In the case of patients:
- When there is any serious injury to the body regions to be tested

- Severe comorbidity including but not limited to cystic fibrosis, cancer, inflammatory bowel disease; history of drug or alcohol abuse; severe psychiatric disorder or dysfunction (e.g., major depression or generalized anxiety disorder)
- Inability to understand the instructions;In the case of healthy controls:
- When there is any serious injury to the body regions to be tested
- Health problems requiring medical treatment, history of drug or alcohol abuse; severe psychiatric disorder or dysfunction (e.g., major depression or generalized anxiety disorder)
- Inability to understand the instructions

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-04-2014
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO Date:	10-01-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-07-2014
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-12-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL44699.041.13