Biomarker Profiling of Pain in Juvenile Idiopathic Arthritis

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

Summary

ID

NL-OMON42093

Source
ToetsingOnline

Brief title
BioProPain in JIA

Condition

- Autoimmune disorders

Synonym
Juvenile idiopathic arthritis, juvenile rheumatoid arthritis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: biomarkers, GRK2, JIA, pain

Outcome measures

Primary outcome

The main endpoint is the difference in pain rating between baseline, i.e. time of diagnosis, (t0) and at 3 (t1), 6 (t2) and 12 months (t3) after diagnosis, dichotomized in clinical relevant change of VAS-score, defined by a change in VAS score of either >= 20 mm or >= 30%.

Secondary outcome

Secondary endpoints are:

1. monocyte/macrophage GRK2 expression

2. LPS-induced monocyte p38 activation

3. cytokine profiles (ratio between pro- and anti-inflammatory cytokine responses)

4. QST profile

5. pain favouring cognition

6. medication (subgroups of medication, NSAID's, MTX, TNF-α blocking biologicals, non-TNF-α blocking biologicals), as a proxy of severity and duration of active JIA

Study description

Background summary

Juvenile idiopathic arthritis (JIA) is a common childhood rheumatic disease which results in long-term disability persisting into adulthood in more than

one-third of the patients. Acute pain is a clinically significant symptom of JIA, and pain persists for months to years in approximately 40% of JIA patients. This persisting, chronic 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.

Study objective

The key objective of this proposal is to develop a prediction tool, which will enable clinicians to detect an increased risk of developing chronic pain in JIA at an early stage of the disease. This tools consists of an assay for GRK2 expression. This prediction tool will enable to tailor the treatment of JIA to minimize the risk of chronification of acute inflammatory pain

Study design

This is a monocenter observational longitudinal study

Study burden and risks

Patients with JIA often suffer from (severe) pain. Being able to identify those patients with JIA who are at risk of developing chronic pain will enable the use of treatment specifically aimed at reducing the transition from acute to chronic pain, without risking overtreatment for the JIA-group at large.
The potential risks are negligible and the burden of study participation is minimal, comparable with the routine physical examination by the pediatric rheumatologist. Sensory tests are all protocolized and considered safe, with no risk of serious injuries. 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. Also, the extra vial of blood taken is timed to coincide with the routine venepuncture as part of standard of care. The questionnaires are chosen to be as concise as possible. 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. There are no costs to the subject for participating in this study. There is no direct benefit for the individual who will participate in the study. The benefits in terms of newly gained knowledge are potentially very valuable as this study will correlate the occurrence of chronic pain to a variety of immunological biomarkers and cognitive determinants.

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

- Age between 6 to 17 years
- Ability to speak and understand Dutch
- having been diagnosed with active JIA by their treating physician as defined by the ILAR-classification
- having the most severe arthritis in either face, hand, knee or foot

Exclusion criteria

- monoarthritis of the hip
- serious injury to the body regions to be tested

- Health problems such as Cystic Fibrosis, cancer, inflammatory bowel disease, drug or alcohol abuse; severe psychiatric disorder or dysfunction (e.g., major depression or generalized anxiety disorder requiring medical treatment)
- Inability to understand the instructions

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2016
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	06-05-2015
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	23-10-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-05-2016
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO Date:	11-10-2017
Application type:	Amendment
Review commission:	METC NedMec

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	NL49224.041.14