Biomarkers for disease activity of juvenile idiopathic arthritis

Published: 30-04-2015
Last updated: 16-04-2024

Our primary goal is to evaluate the individual and interdependent value of optimized 3.0T imaging and immunological biomarkers for the evaluation of disease activity in JIA, compared to clinical examination.

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

Summary

ID

NL-OMON42570

Source
ToetsingOnline

Brief title
Biomarkers in JIA

Condition

- Autoimmune disorders
- Joint disorders

Synonym
Childhood Arthritis, Juvenile Idiopathic Arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: 3T-MRI, biomarker, juvenile idopathic arthritis

Outcome measures

Primary outcome

The accuracy, validity, correlation, predictive value and responsiveness to

change of physical examination, imaging and biomarkers for the clinical course

in JIA patients.

Secondary outcome

The construction of a prediction model in JIA disease activity

The evaluation of high resolution, 3.0T MRI characteristics in the different

JIA subtypes

Study description

Background summary

Juvenile idiopathic arthritis (JIA) is a chronic inflammatory disease of the joints in childhood with a prevalence between 16 and 150 per 100.000 children. JIA encompasses different forms of arthritis with unknown etiology and pathophysiology and is characterized by prolonged synovial inflammation that can lead to destruction of joints, pain and loss of function. The increasing evidence that early therapeutic intervention improves long-term outcome highlight the need for objective and accurate measures in the assessment of disease activity, individual response to therapy, efficacy of treatment and longer-term outcomes in JIA.
Currently, diagnosis and disease activity assessment take place through standard clinical measures: physical examination, blood tests and imaging (conventional radiography and Magnetic Resonance Imaging (MRI)). None of these are as yet considered as a gold standard. Recently promising results in JIA have been achieved with serum biomarkers in the assessment of immune activation. Having a potentially prognostic value in predicting flares or prolonged remission of the disease. Analysis of these and other biomarkers - in combination with state of the art, high resolution, 3.0 Tesla (3.0T) MRI and standard physical examination measures - is necessary to determine the value of

each of these measures in assessing disease activity.

Study objective

Our primary goal is to evaluate the individual and interdependent value of optimized 3.0T imaging and immunological biomarkers for the evaluation of disease activity in JIA, compared to clinical examination.

Study design

Prospective study

Study burden and risks

In addition to current clinical care - which includes physical examination, blood sampling, conventional radiography and MRI - a supplementary 10mL blood will be taken (serum, genetic profiling) and is therefore minimally invasive.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Clinically suspected JIA or diagnosed with JIA.
Scheduled to undergo MRI of the affected joint.
Written informed patients (when >12 years of age) and parental consent
OR
JIA patients with clinically inactive disease for at least 6 months.
A history of clinical evident arthritis in at least 1 joint.
Scheduled to undergo MRI of knee, hand/wrist, ankle or SI joint.
Written informed patients (when >12 years of age) and parental consent.

Exclusion criteria

Age <8 and >18 years.
General contraindications for MRI (such as renal insufficiency, pregnancy and claustrophobia)
Lack of written informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-05-2015
Enrollment:	200

Type:	Actual

Ethics review

Approved WMO Date:	30-04-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL52625.018.15