Optimizing Ankle Imaging 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-OMON50460

Source
ToetsingOnline

Brief title
Ankle imaging 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: Ankle and foot joints, Juvenile Idiopathic Arthritis (JIA), Magnetic resonance imaging (MRI), Ultrasound (US)

Outcome measures

Primary outcome

- To develop and validate a Juvenile Arthritis MRI Score (JAMRIS) for the ankle.

- To develop and validate a US imaging protocol specified for the ankle

affected by JIA

Secondary outcome

- To evaluate the accuracy, validity, correlation, predictive value and

responsiveness to change of optimized 3.0T MR imaging and ultrasound for the

evaluation of disease activity in the ankle of patients with JIA, compared to

the clinical examination as the reference standard.

- To evaluate the differences and similarities of US and optimized 3.0T MRI

between three clinical subgroups, defined as clinically active, inactive or

remitting (see also under 4.1).

- To assess the diagnostic accuracy of DWI in the evaluation of disease

activity (synovitis) in JIA as compared to contrast-enhanced MRI as the

reference standard.

- To assess the diagnostic accuracy of UTE in the evaluation of tendinopathy

compared to contrast-enhanced MRI as the reference standard.

(researchprotocol pages 11, 12 &18)

Study description

Background summary

The ankle is the second most affected joint in children suffering of juvenile idiopathic arthritis (JIA). Involvement of the ankle joint in the disease process is associated with a less favorable outcome. Foot function can be well preserved when optimally treated. Accurate and objective assessment of disease activity in the ankle is therefore of great importance.

Study objective

Our primary goal is to develop and validate a Juvenile Arthritis MRI Score (JAMRIS) for the ankle. Secondly, to evaluate the individual and interdependent value of optimized 3.0 Tesla magnetic resonance imaging (MRI) and ultrasound (US) for the evaluation of disease activity in the ankle of patients with, or suspected for having JIA, compared to the clinical assessment and a selection of blood biomarkers.

Study design

Prospective study

Study burden and risks

In addition to current clinical care - which includes physical examination, blood sampling, conventional radiography and MRI * an ultrasound is scheduled on the same day as the MRI and is therefore minimally invasive. The risks associated with participation in this study are negligible.

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

* Clinically (suspected) active JIA with ankle involvement OR clinically inactive JIA / JIA patients in remission with ankle involvement attributed to JIA in the past
* Scheduled to undergo MRI of the ankle
* Written informed patients (when >12 years of age) and written informed parental consent.
The parental consent of patients older than 16 years of age will become obsolete when the proposed amendment to the Medical Research Involving Human Subjects Act (WMO), which lowers the age limit of parental consent to 16 years, is adopted.

Exclusion criteria

* Age <8 and *18 years.
* A history of intra-articular corticosteroids injection within the last 6 months.
* The need for anesthesia during the MRI examination.
* 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):	28-02-2017
Enrollment:	113
Type:	Actual

Ethics review

Approved WMO

Date:	14-10-2016
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	NL58057.018.16