Pixel-by-Pixel analysis of Dynamic Contrast-enhanced MRI curve patterns in Juvenile Idiopathic Arthritis

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The primary objective is:* to assess the accuracy of DCE-MRI in detecting joint inflammation as compared to physical examination in the evaluation of different stages of disease activity in JIA patients The secondary objectives are:* to evaluate the...

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

Summary

ID

NL-OMON36487

Source
ToetsingOnline

Brief title
DCE-MRI 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: Dynamic MRI, Juvenile Idiopathic Arthritis

Outcome measures

Primary outcome

The accuracy of DCE-MRI in differentiating different stages of disease activity

as compared to physical examination

Secondary outcome

n.v.t.

Study description

Background summary

Juvenile Idiopathic Arthritis (JIA) is one of the most common chronic diseases in childhood and represents one of the leading causes of pediatric acquired disability. It 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 and the development of effective treatments 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.
At this moment evaluation of disease activity is done by a complete work-up comprised of clinical history, physical examination, laboratory assessments and imaging studies. Magnetic Resonance Imaging (MRI) is considered the superior imaging technique assessing disease activity of the joints, using intravenous Gadolinium (Gd) contrast which accurately shows presence, extension and localization of inflammatory joint disease. Gd is an extracellular contrast agent that rapidly passes from the vasculature into the extravascular-extracellular space and in that way produces synovial enhancement, which is associated with disease activity. Dynamic Contrast-Enhanced MRI (DCE-MRI) is the preferred method to objectively determine the enhancement after administration of intravenous contrast medium. In DCE-MRI, images are acquired during the delivery of contrast in the tissue of interest, highlighting the dynamic response of the tissue to the inflow of blood. DCE-MRI can provide valuable information about disease activity by analyzing the Time Intensity Curve (TIC) shapes and distribution patterns of TICs in the synovial membrane.

Previous study of the AMC radiology group has shown that DCE-MRI can be used to distinguish patients with Rheumatoid Arthritis (RA) from control subjects, as correlations were found between clinically active disease and more quickly enhancing pixels, meaning a stronger vascularization in RA patients. Therefore, we expect that this new semi-quantitative analysis method show different TIC shape distribution patterns in different stages of disease activity in JIA patients and, therefore, can provide valuable information about disease activity.

Study objective

The primary objective is:
* to assess the accuracy of DCE-MRI in detecting joint inflammation as compared to physical examination in the evaluation of different stages of disease activity in JIA patients
The secondary objectives are:
* to evaluate the value of DCE-MRI in predicting the clinical course in 1 year time in JIA patients
* to evaluate the enhanced value and reliability of DCE-MRI as compared to static contrast-enhanced MRI in detecting synovial inflammation in JIA
* to evaluate the correlation between DCE-MRI parameters and laboratory assessments of inflammatory parameters.

Study design

Prospective observational

Study burden and risks

Patients will undergo a complete work-up comprising of clinical history, physical examination, laboratory assessments, radiographs and an open-bore MRI-scan with intravenous contrast medium as part of their clinical investigation:
1. An additional dynamic sequence will be added to the regular MRI scan (extra scan time 7 minutes).
2. An additional 10 milliliters of blood will be taken during standard blood sampling.
No side-effects or risks have been reported on MR imaging, provided contraindications are taken in consideration. As intravenous contrast medium is given, patients can have EMLA cream (lidocaïne and prilocaïne, Astra Zeneca, the Netherlands) to anaesthetize the skin before insertion of the standard intravenous cannula

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105AZ Amsterdam
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 with knee involvement.
Scheduled to undergo an open-bore MRI.
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 knee.
Scheduled to undergo an open-bore MRI.
Written informed patients (when >12 years of age) and parental consent

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:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2011
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

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	NL34230.018.10