Diffusion-weighted MRI in Juvenile Idiopathic Arthritis

Published: 19-12-2012 Last updated: 26-04-2024

Primary objectives are: To assess the diagnostic accuracy of DWI in the evaluation of disease activity in JIA as compared to contrast-enhanced MRI as the reference standard. To assess the accuracy of DWI in detecting joint inflammation as compared to...

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

Summary

ID

NL-OMON47139

Source ToetsingOnline

Brief title DWI 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: Diffusion-weighted MRI, Juvenile Idiopathic Arthritis, Knee

Outcome measures

Primary outcome

The diagnostic accuracy of DWI in the evaluation of disease activity in JIA as compared to contrast-enhanced MRI as the reference standard.

The accuracy of DWI in detecting joint inflammation as compared to the physical examination in the evaluation of different stages of disease activity in JIA patients.

Secondary outcome

The correlation between DWI and semi-quantitative scores of synovial

hypertrophy using the Juvenile Arthritis MRI Scoring (JAMRIS) system (at

baseline and at two-year follow-up).

The degree of association between DWI parameters and scores obtained from the

physical examination (at baseline and at two-year follow-up).

The correlation between DWI parameters and laboratory assessments of

inflammatory parameters (at baseline and at two-year follow-up).

The value of DWI in predicting the clinical course in 1 year time in JIA

patients.

The responsiveness to change of DWI parameters.

Study description

Background summary

JIA is not a single disease, but a term that encompasses all forms of arthritis that begin before the age of 16 years, persist for more than 6 weeks, and are of unknown etiology and pathophysiology. Studies in developed countries have reported a prevalence that varies between 16 and 150 per 100.000. Therefore, it is the most common chronic disease 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 highly 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.

Current measures used to assess disease activity in IIA largely rely on unreliable clinical symptoms, joint examination findings, and laboratory measures, and are not accurate in the evaluation of inflammatory disease in JIA. Within the past 10 years, the use of magnetic resonance imaging (MRI) and advances in MRI techniques have substantially improved the evaluation of joint pathologies in JIA patients. To date, contrast-enhanced MRI is the most sensitive imaging modality for the assessment of synovial hypertrophy, the most critical hallmark of disease activity in JIA, as well as in the detection of destructive changes of cartilage and bone. Contrast-enhanced MRI is MRI with the use of an intravenous contrast agent (Gd). Gd facilitates better differentiation between joint effusion and synovial hypertrophy through better visualization of the hypervascularity of the inflamed synovial membrane, reflecting ongoing inflammation. However, the use of Gd markedly prolongs the examination time and increases costs and patient discomfort, due to longer examination time and the risk of allergic reactions to the intravenous contrast agent, which may further reduce the feasibility of MRI in pediatric JIA patients. Therefore, the development of new non-invasive MRI techniques which can be used for the evaluation of early inflammatory changes in JIA is warranted. Diffusion-weighted MR Imaging (DWI) is such a non-invasive technique.

DWI makes use of the random movement of water molecules. In a totally unrestricted environment, water movement would be completely random: Brownian motion or free diffusion. Within tissues, the movement of water is not completely random, but hampered by interaction with tissue compartments, cell membranes, and intracellular organelles. The extent of tissue cellularity and the presence of intact cell membranes help determine the impedance of water molecule diffusion. Tissue types that have been reported to be associated with impeded diffusion include tumor, cytotoxic edema, abscess, and fibrosis. Tissues with low cellularity or that consist of cells with disrupted membranes permit greater movement of water molecules. DWI is primarily used in neurologic and oncologic diseases, though it can be used for evaluating musculoskeletal pathology. In adults it has been demonstrated that DWI preformed as well contrast-enhanced MRI in the evaluation of synovial hypertrophy. Therefore we hypothesized that DWI can be used for the evaluation of disease activity in JIA patients.

Study objective

Primary objectives are:

To assess the diagnostic accuracy of DWI in the evaluation of disease activity in JIA as compared to contrast-enhanced MRI as the reference standard. To assess the accuracy of DWI in detecting joint inflammation as compared to the physical examination in the evaluation of different stages of disease activity in JIA patients.

Secondary objectives are:

To evaluate the correlation between DWI and semi-quantitative scores of synovial hypertrophy using the Juvenile Arthritis MRI Scoring (JAMRIS) system (at baseline and at two-year follow-up).

To evaluate the degree of association between DWI parameters and scores obtained from the physical examination (at baseline and at two-year follow-up). To evaluate the correlation between DWI parameters and laboratory assessments of inflammatory parameters (at baseline and at two-year follow-up). To evaluate the value of DWI in predicting the clinical course in 1 year time in JIA patients.

To evaluate the responsiveness to change of DWI 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 diffusion-weighted MRI (DWI) sequence will be added to the regular MRI scan (extra scan time 6 minutes)

2. Two tubes of blood will be taken during standard blood sampling.

At two-year follow-up, patients again will undergo a work-up comprising of clinical history, physical examination, laboratory assessments, and an open-bore MRI-scan with intravenous contrast medium as part of their clinical

investigation:

1. An additional diffusion-weighted MRI (DWI) sequence will be added to the regular MRI scan (extra scan time 6 minutes)

2. Two tubes of blood will be taken during standard blood sampling.

No side-effects or risks have been reported on MR imaging, provided containdications are taken into consideration.

Contacts

Public Academisch Medisch Centrum

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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 JIA with knee involvement / JIA patients with remitting disease and knee involvement.

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Scheduled to undergo 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 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:	Recruitment stopped
Start date (anticipated):	13-11-2013
Enrollment:	185
Туре:	Actual

Ethics review

Approved WMO	
Date:	
Application type:	

19-12-2012

First submission

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Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-09-2018
Application type:	Amendment
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 CCMO **ID** NL41846.018.12