Magnetic resonance imaging of the healthy pediatric knee and wrist: defining normal values for synovial thickness.

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Primary ObjectiveTo define normal values for synovial thickness in the healthy pediatric knee and wrist on MRI after intravenous gadolinium contrast administration. Secondary ObjectiveTo evaluate possible age-dependent variations in normal values...

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

Summary

ID

NL-OMON39297

Source
ToetsingOnline

Brief title
STIC-study
(Synovial Thickness In Children)

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: Children, MRI, Normal values, Synovial thickness

Outcome measures

Primary outcome

Normal values for synovial thickness on 6 locations in the healthy knee or

wrist of children on MRI after IV contrast.

Secondary outcome

Correlation of normal values for synovial thickness on MRI between two

age-dependent subgroups (8-12 and 13-18 years) on MRI after IV contrast

Study description

Background summary

Juvenile idiopathic arthritis (JIA) is not a single disease, but a term that includes all chronic rheumatic diseases of childhood, beginning for the age of 16, persistent for more than 6 weeks and of unknown etiology and pathophysiology. It is characterized by prolonged synovial inflammation that can lead to the destruction of joints, pain and loss of function. The prevalence in developed countries varies between 16 and 150 per 100.000, making JIA one of the leading causes of pediatric acquired disability4. The evidence that early therapeutic intervention improves long-term outcome increases. If patients need to be treated in an earlier stage, complete comprehension of disease status by means of objective disease activity parameters is necessary. Besides a complete work-up of clinical history, physical examination and laboratory tests, imaging studies are very important in the assessment of disease status. Synovial hypertrophy, a critical hallmark of disease activity and present in early stages of JIA, is most accurately depicted by MRI after IV Gd contrast injection, because the enhancement after Gd differentiates between joint effusion, fibrous tissue and inflamed synovium. To optimize the objective assessment of disease activity and increase utility of MRI as the superior

imaging technique in JIA, a standardized protocol like a MRI scoring system is expedient. As JIA concerns children and their growing skeleton, some MRI findings are part of maturation process in children and should not be mistaken for joint pathologies. Therefore a complete comprehension of the normal anatomy of the growing skeleton is required for the development of a MRI scoring system. Müller et al. (2011) reports about the pediatric wrist of healthy subjects and MRI features like joint fluid, bony depressions and medullary signal changes. Yet on the synovium, as primary target of disease, no cut-off values to differentiate between low-grade arthritis and normal have been determined. Semi-quantitative terms describing the extend of synovial hypertrophy do not suffice as objective disease activity parameters. A proper and objective distinction between pathologic and normal synovium can only be made with the measurement of synovial thickness after enhancement. Therefore it is necessary to gain knowledge on the normal values for synovial thickness on MRI in healthy children. There exist several studies reporting about mild enhancement of synovial tissue in the wrists of healthy adults. To the best of our knowledge, no reports on synovial enhancement or thickness on MRI after IV Gd contrast in children have been published.
As MRI with IV Gd contrast is considered as an invasive imaging technique in children, we chose to conduct this study with a negligible additional burden in patients who are already scheduled for MRI with IV Gd contrast and had an acceptable disease load.

Study objective

Primary Objective
To define normal values for synovial thickness in the healthy pediatric knee and wrist on MRI after intravenous gadolinium contrast administration.

Secondary Objective
To evaluate possible age-dependent variations in normal values for synovial thickness on MRI after intravenous gadolinium contrast administration in children.

Study design

Prospective observational

Study burden and risks

Patients who are already scheduled for an MR Enterography with IV Gd contrast are asked to participate in this study.
1. Patient will be physically examined for any signs of inflammation of the joints before MR Enterography (additional examination time: 10 minutes)
2. Patient has to change position in the MRI scanner to get the knee or wrist positioned in a dedicated knee or wrist coil (additional time to change

position: 3 minutes).
3. One additional MRI sequence will be added at the end of the regular MRI scan (additional scan time: 5 minutes).

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

- Scheduled to undergo an MR Enterography with intravenous gadolinium contrast
- Written informed patients (when >12 years of age) and parental consent.

Exclusion criteria

- Age < 8 and * 18 years.
- Congenital or genetic joint abnormalities (e.g. Down syndrome, Turner*s syndrome).
- A history of trauma of the wrist and the knee.
- Any arthritic diseases (e.g. JIA, systemic lupus erythematosus, mixed connective tissue disease).
- Other chronic conditions affecting the skeleton (e.g. growth hormone deficiency, hypothyroidism).
- Current use of immunosuppressive medication (e.g. prednisone, azathioprine).
- Signs of any joint inflammation during physical examination.

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):	24-07-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	06-03-2012
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	NL39331.018.12