Can we improve the management of Juvenile PsA patients by using a different disease activity measure?

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Primary goal: to determine whether a combined disease activity measure correlates better with disease burden than the current disease measure. Primary study question: does the minimal disease activity JADAS (MDA-JADAS) correspond to the MDA...

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

Summary

ID

NL-OMON51719

Source
ToetsingOnline

Brief title
Key disease activity markers in Juvenile PsA

Condition

- Autoimmune disorders
- Joint disorders
- Epidermal and dermal conditions

Synonym
juvenile arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: disease activity, juvenile arthritis, psoriasis

Outcome measures

Primary outcome

MDA-JADAS

JADAS adds the active joint count (selection of 27 joints out of total of 71 joints), vas global physician, vas global child and ESR together in a total score. The cutoff for classification of minimal disease activity is 2 for oligoarticular JIA and 3.8 for polyarticular JIA, (25)

MDA-PsA

The subjects achieving minimal disease activity (MDA), is defined as 5 of the following 7 domains: <= 1 tender joint count (68 maximum), <= 1 swollen joint count (68 maximum), PASI <= 1 or BSA <=3%, patient pain VAS <= 15, patient global assessment of disease activity VAS <= 20, CHAQ-DI© <= 0.5, tender entheseal points <= 1.

Secondary outcome

Disease burden, functioning, quality of life and participation in society, as experienced by the patient, evaluated by means of PROMs.

Study description

Background summary

Juvenile Idiopathic Arthritis, (JIA) is the most common autoimmune disease in children with inflammation of the joint (arthritis). JIA is a chronic autoimmune disease of unknown cause, and disease onset is before the age of 16. Different subtypes belong to this umbrella term. The combination of arthritis with psoriasis is classified as Juvenile Psoriatic Arthritis (juv PsA).
According to the ILAR criteria, also children without psoriasis but having arthritis in combination with at least two of the following symptoms belong to the subtype juvenile PsA: dactylitis; nail pitting or onycholysis or psoriasis in a first-degree relative.
Other subtypes of JIA are: systemic arthritis; oligo-articular subtype (1-4 joints), persistent and extended type; poly articular rheumatoid factor negative and poly articular rheumatoid factor positive subtype and enthesitis related type. The unclassified subtype of JIA, consists of patients who are excluded from other subtypes.

To evaluate disease activity and effectiveness of (drug) treatment in pediatric patients with children with psoriasis, several separate scoring methods for skin and arthritis are in use. The most commonly used tools for arthritis are: the ACR pedi composite score, which comprises the physician global assessment of disease activity, parent/patient assessment of overall well-being, functional ability, number of joints with active arthritis, number of joints with limited range of motion; and erythrocyte sedimentation rate. A more compact size, without functionality measurement and number of restricted joints , is the Juvenile Arthritis Disease Activity Score (JADAS) (10-27-71 joints). This tool consists of physician global assessment of disease activity, parent/patient assessment of overall well-being, number of joints with active arthritis; and the erythrocyte sedimentation rate or C-reactive protein. The advantage of using one of these tools, is the ability to evaluate patients burden (vas general well-being) as well as arthritis, which makes it possible to compare with the other subtypes of JIA with juv PsA. Comparison between subtypes might be important as up to 14% of the patients are reclassified to another subtype during follow-up.

Skin involvement of (juvenile) psoriasis is an important marker for disease activity, as this is one of the most important co-morbidities in young adults with Juv PsA. Quantitative scoring of skin severity in dermatological oriented literature includes calculation of the Psoriasis Area and Severity Index (PASI). Other tools are the body surface area (BSA) and the Physician Global Assessment. From all of these above mentioned scores, the PASI is recommended in current consensus guidelines as the most thoroughly validated score and can be recommended for quantitative evaluation of clinical severity of psoriasis. Patient Reported Outcome Measurement tools (PROM*s) in pediatric psoriatic patients are the Simplified Psoriasis Index (SPI) and the Dutch version of the Children*s Dermatology Life Quality Index (CDLQI).
In addition to arthritis and skin involvement, other additional symptoms in children with juv PsA are: enthesitis (30%), inflammatory bowel disease, sacroiliitis or inflammatory low backpain (17%) and uveitis (11%). The presence

of psoriasis, sacroiliitis, and uveitis indicates a worse prognosis, as a lower percentage of patients will remain a medication-free longterm remission. In the majority of Juv PsA patients (50-70%), the disease is still active or there are consequences of the disease in adulthood. This may be attributed to under-treatment, as not all symptoms which are associated with juv PsA, including the presence of enthesitis, dactylitis or nail-involvement, are identified using currently validated disease activity tools.
In line with the recommendations of the World Health Organization (WHO), not only disease related outcome, but also effect on functioning and participation in daily practice are important to evaluate. These recommendations are summarized in the International Classification of Functioning, Disability and Health, commonly known as ICF framework. (ref International Classification of Functioning, Disability and Health (ICF); www.who.int/classifications/icf/en/).
The relatively unfavorable prognosis of Juv PsA in functioning is described by Scandinavian colleagues, where after long-term follow-up, lower scores on the SF 36 (physical functioning) were found compared to oligo or poly articular JIA.
In adult care, the various symptoms, seen in patients with PsA, are combined into a composite measure, to evaluate disease activity, burden and effect of treatment. Examples of these validated and internationally recommended composite measures are the GRAPPA composite index and the PsA disease Activity Score Index. Standardizing outcome measurement will improve the evaluation of the effects of treatment and long term outcome.
However, to date, composite measures do not exist for juv PsA patients.

Due to the relatively high prevalence of PsA (1.5-2% in Northern Europe) and the fact that psoriasis starts in childhood in about 25%, it is important to develop adequate, preferably composite , validated disease activity scores, to detect all symptoms that determine the prognosis and treatment of PsA., with an early onset at childhood.

In this study, we would like to compare a composite disease activity tool with the commonly used Juvenile Arthritis Disease Activity Score, in juvenile patients with a probable or definite PsA.
Further on, we would like to investigate:
-which PsA specific symptoms are present in JIA patients
-to evaluate the burden of the disease
-idealiter, when follow-up of this cohort is possible, to evaluate the characteristics and outcome of those patients who will develop definite Juv PsA

Study objective

Primary goal: to determine whether a combined disease activity measure correlates better with disease burden than the current disease measure.

Primary study question: does the minimal disease activity JADAS (MDA-JADAS)

correspond to the MDA psoriasis?

Secondary:
-Mapping which PsA specific components are present in Juvenile Arthritis patients.
-Burden of JIA, in specific Juvenile PsA, reflected in PROM*S

Study design

This is a cross sectional obseravtional study of patients diagnosed with several subtypes of JIA, visiting the jongerenpoli (adolescent clinic) of the department rheumatology of the Erasmus MC outpatient clinic. Patients participating will have their regular clinical consult with the pediatric rheumatologist (phvp) for observation of disease features, including PROM*s (patient reported outcome measurements), physical examination, regular blood testing and imaging when indicated. In addition patients will be investigated for enthesitis using ultrasound. In case of (probable) involvement of skin and nails, the (pediatric) dermatologist will be asked for consultation.

Study burden and risks

The disease activity parameters are obtained from the regular outpatient visit. The questionnaires (PROMs) are currently regularly taken prior to the outpatient visit. Completing the digital available questionnaires takes about 45-60 minutes. When patients are participating in the study, data necessary for study purposes, data will be kept in an encrypted database. No specific questions are asked for this study that could cause psychological or emotional harm to the participant. For patients under the age of 18, in addition to the consent of the patient, also consent of the parents/ legal guardians will be requested. Evaluation of the enthesis by ultrasound will take approximately 30 minutes extra time.
In view of the above, the risk of damage to the participant is negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

patients of the outpatient department of the Erasmus MC diagnosed with possible Juvenile PsA including the subtypes:
- Juvenile PsA,
- Oligoarticular JIA,
- Polyarticular rheumatoid factor negative JIA
- Enthesitis related JIA
- Undifferentiated JIA
- Age between the ages of 12 and 24
- Patients must be able to understand and communicate with the Investigator and comply with the requirements of the study
- Patients and/or legal guardian must give a written, signed and dated informed consent before any study assessment is performed.

Exclusion criteria

- not willing to participate
- uncapable of understanding Dutch language

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-05-2022
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	29-04-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL79400.078.21