MD-PAEDIGREE: Model-Driven European Paediatric Repository - WP 5: Data acquisition and processing for Juvenile Idiopathic Arthritis

Published: 12-03-2014
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To collect demographic, clinical, therapeutic, microbiotic and imaging data in patients with JIA, to build a repository, to find novel biomarkers and to construct computerized models to predict the prognosis in children with JIA af the time of...

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

Summary

ID

NL-OMON41380

Source
ToetsingOnline

Brief title
MD-Paedigree - WP5

Condition

- Autoimmune disorders

Synonym
juvenile idiopathic arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Ospedale Pediatrico Bambino Gesù

Source(s) of monetary or material Support: Europese Commissie (FP7 grant)

Intervention

Keyword: data repository, disease modelling, juvenile idiopathic arthritis, prognosis

Outcome measures

Primary outcome

The development of damage (intra-articular or extra-articular) according to the validated juvenile arthritis damage index (JADI).

Secondary outcome

Disease remission according to Wallace criteria, the juvenile arthritis disease activity score (JADAS), functional ability (childhood health assessment questionnaire [CHAQ] score), disease activity according to the American College of Rheumatology (ACR) pediatric criteria. The development of radiological damage in children with ankle involvement. The number of flares.

Study description

Background summary

Juvenile Idiopathic Arthritis (JIA) is the most common rheumatologic disorder in children. It is characterized by arthritis of unknown etiology, manifesting itself before 16 years of age and lasting at least 6 weeks. JIA is a heterogeneous disorder, which is being divided into a number of subtypes. The prognosis of JIA is highly variable, not only among subtypes, but also among patients with the same subtype. At present, it is impossible to accurately predict the prognosis in an individual patient.

Study objective

To collect demographic, clinical, therapeutic, microbiotic and imaging data in patients with JIA, to build a repository, to find novel biomarkers and to construct computerized models to predict the prognosis in children with JIA af

the time of diagnosis.

Study design

A prospective, observational cohort study.

Study burden and risks

The risk is estimated to be low: the procedures performed during the study are part of the standard of care, which means that they are also applied to children with juvenile idiopathic arthritis who do not participate in this study.
The burden is estimated to be low. There is no psychological burden, no unfavorable, traumatic results (because no tests for conditions or diseases will be performed). The only investment for participants will be the additional time they will have to spend in the hospital during visits.

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

Children and adolescents with JIA according to ILAR criteria and disease duration < 6 months.
Parents or legal guardian (and the subject when age is appropriate) must be willing to sign the consent/assent forms.
Age-matched healthy subjects willing to collect a stool sample.

Exclusion criteria

None

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-03-2014
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	12-03-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-12-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-07-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL46068.041.13