BRAVOO study
Better understanding of reactive arthritis in children to prevent overtreatment and unnecessary consumption of care

Published: 02-10-2020
Last updated: 09-04-2024

The aim of this study is to determine the known and unknown pathogens of reactive arthritis in children between six months to 18 years old. We will use a protocolized approach of diagnostic testing in order to develop an evidence based clinical...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON54224

Source
ToetsingOnline

Brief title
BRAVOO study

Condition

- Joint disorders

Synonym
arthritis, inflammation of the joint

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis

Source(s) of monetary or material Support: Stichting Beter Keten (www.beterketen.nl);initiatief van Maasstad Ziekenhuis;Albert Schweitzer Ziekenhuis;Franciscus Gasthuis en Vlietland;Erasmus Medisch Centrum

Intervention

Keyword: Arthritis, Childhood, Diagnostics, Pathogens

Outcome measures

Primary outcome

This is an observational cohort study, in which we aim to answer five research questions during emergency department/outpatient clinic visits for routine clinical care. The study will lead to the following main study endpoints:

1. Determine the role of currently known pathogens in children with arthritis.

2. Determine whether anti-streptolysine O and DNAse-B testing is a reliable method to diagnose post-streptococcal reactive arthritis.

3. Investigate the link between Mycoplasma pneumoniae and childhood arthritis using a new diagnostic method.

4. Using "viral meta-genomics" to investigate whether unknown viruses can be associated with reactive arthritis in children.

5. Developing an evidence-based (inter) national guideline for the diagnosis of arthritis in children.

Secondary outcome

-

Study description

Background summary

Immune-mediated or reactive arthritis is the most common form of arthritis in children. In this case, inflammation in the joint is caused by an ongoing immune response following a bacterial or viral infection elsewhere in the body. This is a mild form of arthritis that is treated with non-steroidal anti-inflammatory drugs (NSAID*s) and occasionally with intra-articular injections with corticosteroids. Less common are the other two most common types of arthritis in children: bacterial arthritis that requires a hospital stay and rapid intravenous antibiotics to prevent severe joint damage and Juvenile Idiopathic Arthritis (JIA). JIA is diagnosed if the arthritis is present for more than six weeks and no other (microbial) causes have been identified. The children with JIA are referred to an academic center where long-term treatment and follow-up take place. The problem is that we are currently unable to properly distinguish these three types of arthritis, mainly because reactive arthritis is not well recognized with current diagnostic tests.

Study objective

The aim of this study is to determine the known and unknown pathogens of reactive arthritis in children between six months to 18 years old. We will use a protocolized approach of diagnostic testing in order to develop an evidence based clinical diagnostic guideline. By identifying pathogens leading to reactive arthritis and excluding bacterial arthritis and JIA, reactive arthritis can be diagnosed in an early stage followed by adequate treatment.

Study design

Multicenter prospective observational study.

Study burden and risks

As part of routine clinical care, the following diagnostics will be carried out:

- Blood test on day 0, and optionally on day 14 and day 28-42.
- Nasopharyngeal swabs.
- Throat culture.
- Stool test.
- Synovial fluid analysis (only on indication).
- Radiology: conventional X-ray of the affected joint and, if indicated, ultrasound of the affected joint / MRI of the affected joint.

The following study procedures will take place:
- Extra blood or synovial fluid when blood or synovial fluid is collected as part of routine clinical care. Blood will be taken up to 3 times for the study

over a six-week period. The blood sampling will remain within the limits of the WHO guidelines on peripheral blood sampling for minors of 2015 (~0,8 ml/kg/sampling time with a maximum of 50 ml/draw, not exceeding six times a year).
- Nasopharyngeal swabs will be taken during outpatient visits (maximum three times).
- Patients will complete a short questionnaire regarding quality of life at the first visit, at six weeks and at 12 weeks after diagnosis.

With these study procedures, we estimate the burden and risk to the patient as minimal.

Contacts

Public
Maasstadziekenhuis

Maasstadweg 21
Rotterdam 3079DZ
NL
Scientific
Maasstadziekenhuis

Maasstadweg 21
Rotterdam 3079DZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

-First presentation of arthritis with a maximum duration of six weeks
-Children from six months - 18 years of age

Exclusion criteria

-Patients already known with juvenile idiopathic arthritis or any diagnosis that is related with arthritis (for example IgA vasculitis)
-Patients known with immunodeficiency disorders
-Insufficient understanding of Dutch language

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2021
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	02-10-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	09-05-2023
Application type:	Amendment
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	NL73543.078.20