

The long-term clinical outcomes and radiological sequelae of acute septic arthritis in children.

Published: 03-05-2024

Last updated: 11-07-2024

To assess the long-term clinical outcomes using Patient-reported Outcome Measures (PROMS), physical examination and radiological sequelae of acute septic arthritis in children.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON56874

Source

ToetsingOnline

Brief title

Long-term outcome of acute septic arthritis in children

Condition

- Bacterial infectious disorders
- Joint disorders

Synonym

infectious arthritis, joint infection

Research involving

Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis

Source(s) of monetary or material Support: Annafonds

Intervention

Keyword: children, long-term outcome, septic arthritis

Outcome measures

Primary outcome

The patient-reported outcome measures (PROMs) consist of two general questionnaires and one joint-specific outcome measure

Secondary outcome

During this visit, the range of motion of the affected and contralateral joints, any length discrepancy and growth disturbance will be assessed. X-rays will be made for radiological evaluation of any sequelae, including cartilage degeneration, osteo-arthritis and avascular necrosis.

Study description

Background summary

Acute septic arthritis in children is an orthopaedic emergency. A delay in diagnosis and inappropriate treatment can result in a devastating damage to the joint with lifelong disability as a consequence. The clinical presentation can be a diagnostic challenge, especially in young children. The diagnosis of acute septic arthritis is highly suggestive when pus is aspirated from the joint, in case of a positive culture or a positive gram stain of the joint fluid, or if there is a white blood-cell count in the joint fluid of more than 50000/mm³. Recent systematic reviews have identified the most effective drainage techniques, including needle aspiration, arthroscopy and arthrotomy, depending on the affected joint. However, the studies about the optimal drainage procedure of the several joints were diverse and the scientific quality was generally low. The follow-up was short and low numbers of patients were investigated. Through our proposed research we aim to better inform the patients and their parents about the long-term effects of septic arthritis in children and hopefully improve treatment in the future.

Study objective

To assess the long-term clinical outcomes using Patient-reported Outcome Measures (PROMS), physical examination and radiological sequelae of acute septic arthritis in children.

Study design

Multi-center retrospective cohort study

Study burden and risks

No direct burden or risk (see Summary page 8 protocol).

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)

Children (2-11 years)

Inclusion criteria

- Population: all patients aged between 0 and 17 years during the diagnose of acute septic arthritis
- Treated over a time period from the start of electronic patient records until 2018 in one of the five regional top clinical or academic hospitals.
- The diagnosis of acute septic arthritis have to fulfill at least one of the following criteria:
 1. Pus aspirated from the joint
 2. A positive culture of the joint fluid;
 3. White blood cell count in the joint fluid > 50.000/mm³

Exclusion criteria

1. Intellectually disabled
2. A language barrier
3. No informed consent

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-05-2024

Enrollment: 60

Type: Anticipated

Ethics review

Approved WMO

Date:	03-05-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL84359.100.23