A Paradigm Shift in the Treatment of Bacterial Arthritis of a Native Joint: Needle Arthroscopy

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Primary Objective: To establish the effectiveness of lavage with needle arthroscopy in patients with suspected bacterial arthritis of a native joint. The primary outcome measure is the number of additional invasive interventions -needle aspiration,...

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

Summary

ID

NL-OMON54067

Source
ToetsingOnline

Brief title
Needle arthroscopy for bacterial arthritis

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
arthritis, bacterial arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Amsterdam UMC

Intervention

Keyword: Bacterial arthritis, Effectiveness, Native joint, Needle Arthroscopy

Outcome measures

Primary outcome

The main study parameter is the number of additional interventions needed to control the infection of the affected joint

Secondary outcome

The secondary study parameters (procedure & admission):

- Failure of needle arthroscopy due to e.g.:

• Need for conversion to general or loco-regional anesthesia (e.g. due to the patient not tolerating procedure under local anesthesia)

• Device failure

• Joint not accessible with needle arthroscopy

- The number and nature of adverse events within 3 months

• Local nerve damage

• Bleeding that requires an additional surgical or radiological-intervention procedure to control the bleeding

• Wound infection

• Any adverse events during hospitalization (e.g. pneumonia, thrombosis, myocardial infarction, urinary tract infection, etcetera) that requires an additional surgical procedure, radiological-intervention procedure or medical intervention (e.g. antibiotic treatment) to control the adverse event.

- The number and nature of serious adverse events within 3 months

• Death

• Prolongation of hospitalization

• Severe sepsis

• ICU admission

• Disability or permanent damage (i.e. resulted in a substantial disruption of a person*s ability to conduct normal life functions, resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient*s body function, physical activities and/or quality of life).

• Other serious adverse events (i.e. the event does not fit the other outcomes, but the event may jeopardize the patient and may require medical or surgical intervention to prevent one of the other outcomes.

- Length of hospital stay (as measured as the time between arrival and discharge)

- Time of the intervention (as measured as the time between the camera enters into the joint and the camera goes out of the joint at the end of the procedure)

- Time between patient presentation and needle arthroscopic procedure

- Patient experience during the procedure, as measured with a numeric rating scale (where patients are asked to circle the number between 0 and 10 that fits best to their pain intensity during the procedure)

The secondary study parameters (follow-up visit at 3 months post-procedure):

- Range-of-motion of the joint

- Mortality

- Patient reported outcome measures

• Return to sports / work

• EQ5D-5L written in Dutch and English

• KOOS, Knee Injury and Osteoarthritis Outcome Score, written in Dutch and English (for knee)

• FAOS , Foot and Ankle Outcome score, written in Dutch and English (for ankle)

• PROMIS upper extremity, Patient-Reported Outcomes Measurement Information System, written in Dutch and English (for shoulder, elbow, wrist)

Study description

Background summary

A bacterial infection of a native joint, so-called bacterial or septic arthritis, urgently requires diagnosis and subsequent treatment to control the infection and decrease the risk of joint destruction. Treatment consists of drainage of the affected joint and antibiotic therapy. A large spectrum of techniques to drain the joint has been described; from needle aspiration to open surgical lavage. Whilst it is not clear which treatment strategy is most effective, there is consensus that urgent drainage and antibiotic treatment is needed to avert the imminent threat of sepsis and joint destruction. Clinical assessment, combined with laboratory tests, imaging, and a diagnostic bedside aspiration are part of the standard diagnostic workup. When there is a suspicion of a bacterial arthritis, the patient often undergoes surgery, either arthroscopically or arthrotomy to lavage the joint and take cultures, after which antibiotics are started. However, surgery requires anaesthesia and availability of an operation room, potentially causing diagnostic and treatment delay as well as anaesthesia-related complications.
Recent technical innovation offers the possibility of 2-mm diameter arthroscopy. This so-called needle arthroscopic system is CE-marked and uses a (chargeable) tablet for image processing. The needle arthroscope can be connected to syringes for distention and lavage of the joint. Hence, compared to standard arthroscopy, only limited tools are needed (no arthroscopy tower), allowing it to be moved around the hospital. In addition, only small (2-mm) portals are needed, which might be acceptable for the patient under local anesthesia. Needle arthroscopy is more commonly used in orthopaedic care worldwide, both in the operation room and at the patient bedside, under local anaesthesia. Our research group submitted pilot data on a small cohort (n=11) of patients that underwent bedside needle arthroscopy for bacterial arthritis

of various joints. Data appears promising and we therefore believe that needle arthroscopy is a potential valuable new tool to aid diagnosis and lavage of a joint in a timely fashion, minimizing morbidity from surgery and general anaesthesia. We therefore aim to further evaluate the effectiveness (in terms of avoiding additional interventions to control the infection) of needle arthroscopy in diagnosing and treating suspected bacterial arthritis. In addition, we will evaluate patient experience, clinical outcomes, adverse events, potential risk factors for failure of a single needle arthroscopic lavage, and economic costs.

Study objective

Primary Objective:
To establish the effectiveness of lavage with needle arthroscopy in patients with suspected bacterial arthritis of a native joint. The primary outcome measure is the number of additional invasive interventions -needle aspiration, needle arthroscopy, conventional arthroscopy, arthrotomy, or other procedure (e.g. resection/amputation/arthrodesis/prosthesis)- needed to control the infection of the affected joint. We hypothesize that the effectiveness of lavage with needle arthroscopy should at least be equal (i.e. non-inferior) to lavage with conventional arthroscopy or arthrotomy based on failure rates reported in the literature. The failure rate of conventional arthroscopy or arthrotomy ranges between 8%-38% in the literature.

Secondary Objective(s):
• To evaluate patient experience: numeric rating scale (NRS) questionnaire.
• To evaluate clinical outcome: range of motion of the affected joint, return to sports/work, EQ5D-5L-, KOOS-, FOAS-, and PROMIS upper extremity-questionnaire written in Dutch and English.
• To assess major (e.g. death, severe sepsis, ICU admission, persistent disability or incapacity) and minor (e.g. infection, hematoma, iatrogenic damage to articular cartilage, iatrogenic neurovascular damage) adverse events of needle arthroscopy.
• To evaluate the potential risk factors for failure of a single needle arthroscopic lavage.
• To evaluate associated costs.

Study design

Single centre (departments of Orthopaedic Surgery and Rheumatology & Clinical Immunology of Amsterdam UMC, locations AMC and VUmc), prospective observational cohort study of all patients presenting with a clinical suspected bacterial arthritis of a native joint.

Intervention

All included patients are treated with a joint lavage by needle-arthroscopy

Study burden and risks

Burden & Risk
• Standard risk of (needle) arthroscopy (i.e. infection, hematoma, iatrogenic damage to articular cartilage, iatrogenic neurovascular damage)
• Subsequent conventional surgery (conventional arthroscopy or arthrotomy) may be required to control the infection.
• Failure of needle arthroscopy - necessitating conversion to conventional arthroscopy or arthrotomy - due to for example:
• Need for general/loco-regional anaesthesia (e.g. due to a patient not tolerating procedure under local anaesthesia).
• Device failure
• Joint not accessible
• Pre- and post-procedure questionnaires

Benefit
• Expected decrease in need for conventional surgery (conventional arthroscopy or arthrotomy)
• Procedures can be performed with local or regional anesthesia, potentially minimizing morbidity from general anaesthesia.
• Patients can probably be treated timelier using bedside needle arthroscopic lavage as compared with conventional arthroscopic or arthrotomy lavage requiring an operation room and anesthesia.
• Needle arthroscopy gives more information about the affected joint then (repeated) needle aspiration. In addition, it will be possible to take biopsies for culture and histology.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Patients with clinical suspicions of bacterial arthritis of a native joint of the shoulder, elbow, wrist, knee or ankle who provided informed consent to be included in this study.
- Patients are above 18 years of age
- Is able to understand Dutch or English language

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- A foreign body in the affected joint (e.g. screw, prothesis, anchor, suture)
- History of arthroplasty in the affected joint
- Recent (<3 months) fracture surgery involving arthrotomy with the use of osteosynthesis material in the affected joint
- Acute traumatic open joint fracture or dislocation
- Local osteomyelitis

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):	24-10-2021
Enrollment:	49
Type:	Actual

Medical products/devices used

Generic name:	NanoScope and NanoNeedle
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-10-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-05-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-04-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214

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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21076
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL78387.018.21