Needle arthroscopy for bacterial arthritis

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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.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21076

Source
NTR

Brief title
TBA

Health condition

Bacterial arthritis of a native joint

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

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 within 30 days

Secondary outcome

- 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 Short-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 - To evaluate the diagnostic serum (e.g. serum ESR, CRP, WBC, procalcitonin, blood culture) and synovial fluid (e.g. gram stain, culture, WBC + differential count, glucose, lactate, CRP) modalities for patient with bacterial arthritis

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. Recent technical innovation offers the possibility of 2-mm diameter arthroscopy, so-called needle arthroscopy. Compared to conventional arthroscopy, less equipment is needed. In addition, only small (2-mm) portals are required, which might be acceptable for the patient under local anaesthesia. Hence, needle arthroscopy might be a valuable new tool to aid diagnosis and treatment of a bacterial arthritis in a timely fashion, minimizing morbidity from surgery and general anaesthesia. We hypothesise that needle arthroscopy under local anaesthesia can decrease the need for surgery in patients suspected of a bacterial arthritis of a native joint.

Study objective

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.

Study design

Baseline 3 - month time point follow-up

Intervention

Needle arthroscopy in patients with a clinical suspicion of bacterial arthritis of a native joint

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: - Presents with a clinical suspicion of bacterial arthritis of a native joint of the shoulder, elbow, wrist, knee or ankle - Is able to provide informed consent to be included in this study. - Is 18 years of age or older - 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, anchor, prosthesis, suture). - 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:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2021
Enrollment:	49
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Positive opinion

Date:	20-10-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54067
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9802
CCMO	NL78387.018.21
OMON	NL-OMON54067

Study results

Summary results
10.1186/s40634-021-00384-5