

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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21076

Bron

Nationaal Trial Register

Verkorte titel

TBA

Aandoening

Bacterial arthritis of a native joint

Ondersteuning

Primaire sponsor: Amsterdam UMC

Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Baseline

3 - month time point follow-up

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2021
Aantal proefpersonen:	49
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting

N/A

Ethische beoordeling

Positief advies	
Datum:	20-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54067
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

10.1186/s40634-021-00384-5