# Accuracy of intra-articular injections to the ankle with 2-mm diameter arthroscopy: a pilot study

Published: 04-11-2019 Last updated: 10-04-2024

The primary objective is to confirm the accuracy of 2-mm diameter arthroscopy guided intraarticular injections to the ankle in a patient setting.

| Ethical review        | Approved WMO        |
|-----------------------|---------------------|
| Status                | Recruitment stopped |
| Health condition type | Joint disorders     |
| Study type            | Interventional      |

# Summary

### ID

NL-OMON48310

**Source** ToetsingOnline

Brief title Ankle injections through 2-mm diameter arthroscopy

### Condition

- Joint disorders
- Bone and joint therapeutic procedures

**Synonym** arthritis, osteoarthritis

**Research involving** Human

### **Sponsors and support**

Primary sponsor: Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Arthrex, Het onderzoek wordt gefinancierd vanuit een onafhankelijke onderzoeksbeurs; toegekend aan de afdeling Orthopedie van

1 - Accuracy of intra-articular injections to the ankle with 2-mm diameter arthrosco ... 2-05-2025

Amsterdam UMC door Arthrex GmbH

#### Intervention

Keyword: Accuracy, Ankle, Arthroscopy, Injections

#### **Outcome measures**

#### **Primary outcome**

The main study parameter is injection accuracy. An injection is accurate if it is delivered intra-articular. Intra-articular delivery is confirmed with the arthroscopic view.

#### Secondary outcome

- Patient maximum discomfort during the procedure, as measured by a numeric

rating scale of pain

- Patient preferences if any prior injections to the ankle were delivered by
- conventional injection techniques
- The number and nature of adverse events
- The number and nature of serious adverse events
- Treatment effect as measured by pre- and post-injection differences in:
- \* NRS of pain during rest, walking, running and climbing stairs
- \* AOFAS ankle score as measured by the physician

# **Study description**

#### **Background summary**

Intra-articular injections play an important role in orthopaedic surgery, especially in the treatment of osteoarthritis. Innovative injectables promise to further increase the importance of injections as a modality for minimally invasive treatment. Nonetheless, injection accuracy is often limited at best, especially for smaller joints such as the ankle. Inaccurate injection leads to a lost treatment effect and can have a detrimental influence on extra-articular soft tissue. A novel needle-like arthroscopic system with CE-marking was recently released. This system uses a 2-mm diameter, disposable arthroscope and a tablet-like video console. Despite its substantially smaller diameter, the system obtains high quality images. In a cadaveric setting, the system provided 100% accuracy in intra-articular injections to the ankle, where injections were delivered through the arthroscope itself. That is, injected media flowed between the arthroscope and its cannula into the joint. We hypothesize that with 2-mm diameter arthroscopy, intra-articular injections can likewise be delivered with 100% accuracy in a patient setting.

#### **Study objective**

The primary objective is to confirm the accuracy of 2-mm diameter arthroscopy guided intra-articular injections to the ankle in a patient setting.

#### Study design

Cross-sectional pilot study

#### Intervention

A hyaluronic acid injection is administered to the ankle as planned. The injection is performed trough 2-mm diameter arthroscopy. There is no control group.

#### Study burden and risks

Burden & risks:

- Arthroscope introduction causes a minimally larger (1.2 mm larger) skin incision compared to standard practice

- Pre- and post-injection questionnaires and one additional follow-up visit to the outpatient office

- General injection associated risks (infection, neurvascular damage, cartilage damage)

Benefits:

- Expected increase in injection accuracy and hence an increase of the change of a positive treatment effect

- Decreased change of injection-associated iatrogenic damage to neurovascular structures and intra-articular cartilage

# Contacts

**Public** Academisch Medisch Centrum

Meibergdreef 9 Amsterdam 1105AZ NL Scientific Academisch Medisch Centrum

Meibergdreef 9 Amsterdam 1105AZ NL

# **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:

- Consented to a injection with hyaluronic acid to the ankle as treatment for osteoarthritis

- Is between 18 and 80 years of age
- Is able to understand the Dutch or English language
- Is capable of understanding the nature of the study
- Is able to provide written informed consent
- Agrees to a follow-up visit to the outpatient office

# **Exclusion criteria**

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Active infection at the time of injection or inclusion, either systemic or locally at the planned injection site

- Bleeding disorders

- Excessive difficulty or health risk caused by arthroscope introduction, as

expected by the treating surgeon

- Unavailable on the planned intervention day

# Study design

### Design

| Study type: Interventional |                         |
|----------------------------|-------------------------|
| Masking:                   | Open (masking not used) |
| Control:                   | Uncontrolled            |
| Primary purpose:           | Treatment               |

### Recruitment

. . .

| NL                        |                     |
|---------------------------|---------------------|
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 13-12-2019          |
| Enrollment:               | 25                  |
| Туре:                     | Actual              |

### Medical products/devices used

| Generic name: | NanoScope             |
|---------------|-----------------------|
| Registration: | Yes - CE intended use |

# **Ethics review**

| Approved WMO      |                  |
|-------------------|------------------|
| Date:             | 04-11-2019       |
| Application type: | First submission |

5 - Accuracy of intra-articular injections to the ankle with 2-mm diameter arthrosco ... 2-05-2025

# **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
 NL71185.018.19