Injection technique ankle joint

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The aim of this study is to investigate the efficacy, accuracy and patient satisfaction of intra-articular injections in the osteo-arthritic ankle joint using the traction device compared to the conventional method of injecting.

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

Summary

ID

NL-OMON30079

Source
ToetsingOnline

Brief title
zie boven

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
osteo-arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ankle, Injectiontechnique

Outcome measures

Primary outcome

-Failure rate of the different injection procedures

Secondary outcome

To investigate the effect of traction on the joint space.

To compare patient satisfaction of the injection technique with and without the

traction-device.

To compare the practical value of the injection technique with and without the

traction-device.

Study description

Background summary

Study Rationale

The conventional injection method for injecting the intra-articular joint has a lot of adverse events, most likely injection related, a percentage of 2-47% has been found for the knee joint. 12-15. It has been proved that only 67% of injections in the ankle joint is intra-articular.23
To improve the chance of injecting the ankle intra-articular, a new method was designed and is currently used on our daycare centre.
However this method has not been proved yet, despite the fact that both surgeon and patient seem to be satisfied.
This new method uses a traction device with which we hope to open up the joint to allow easier access with the needle, in literature it has been proved that with the aid of a traction device the joint will open. However this was tested on healthy volunteers and on patients under anesthesia with no or just mild osteo-arthritis. Hyaluronic acid injections are used on patients with varying grades of osteo-arthritis. Osteo-arthritis stiffens the movement of the ankle and osteophytes block the way of the needle.
Therefore this is a much more difficult group to inject intra-articular. The exact dose of hyaluronic acid which the patients need to get an optimal pain relieve has not yet been sustained. Hyaluronic acid needs to be injected intra-articular for an optimum of pain relieve.
We performed a dose finding pilot study, which has not been published yet.

The results of this study however show a discrete tendency to use more than one injection to get more pain relief.

Study objective

The aim of this study is to investigate the efficacy, accuracy and patient satisfaction of intra-articular injections in the osteo-arthritic ankle joint using the traction device compared to the conventional method of injecting.

Study design

A cross-over pilot study in which two injection techniques in the ankle joint will be compared.

Study burden and risks

This investigation uses X-ray to control the placement of the needle with the help of contrast.
The first group of patients (10)who will be injected with the aid of the tractiondevice will also get a measurement of their joint space, with and without the use oftraction.
We will use the rotating C-bow to make a 3D reconstruction before and after traction. to measure the gain in jointspace.
Patients who are allergic to contrast will be excluded.
Follow up will take place one week after each injection, in the case of an adverse event weekly contact will take place untill the event has been.
After each injection patients will be asked to give a VAS score for the pain during injection, after two injections they will be asked,which method they prefered.

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

male or female aged 18 years or older
osteoarthritis of the ankle joint confirmed by X-rays
candidate for hyaluronic acid
informed consent

Exclusion criteria

Known allergic reaction to contrast
Pregnancy or nursing
oral or parenteral anticoagulant therapy

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-06-2006
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL12536.018.06