Joint distraction in the treatment of haemophilic ankle arthropathy: clinical and structural efficacy, a pilot study

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This study is designed to gather prospective data on a) the clinical effectiveness, b) the tissue structure changes, and c) the short term costs of ankle joint distraction (AJD) in 10 patients with HAA during 10 years follow-up.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Interventional

Summary

ID

NL-OMON46992

Source
ToetsingOnline

Brief title
Joint distraction in haemophilic ankle arthropathy

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Joint disorders

Synonym
bleeding disorder, haemophilia

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, Arthropathy, Distraction, Haemophilia

Outcome measures

Primary outcome

Change from baseline to 1 year after distraction in the ankle osteoarthritis scale, a validated questionnaire in degenerative ankle complaints.

Secondary outcome

A) Other clinical parameters - change in functionality measured by questionnaires and functional tests

B) Tissue (bone, cartilage, and soft tissue) structure changes will be measured by imaging (X-ray and MRI), and analysis of biochemical markers of cartilage and bone turnover.

C) Short-term costs (during surgery patients need high levels of expensive clotting factor) is assessed by questionnaires on employment and medical usage, and registration of clotting factor consumption.

D) Quality of life, measured by the EQ-5D questionnaire, also during treatment to assess the psychological burden of the treatment

Study description

Background summary

In the genetic bleeding disorder haemophilia, the most common complication is joint damage due to recurrent joint bleeds. Besides the knees and elbows, ankles are the most affected joints. Nowadays, in youngsters with haemophilia, the ankle joint is the most affected joint. Surgical procedures like arthrodesis (a permanent joint fusion) are often necessary. However, due to the fast progressive joint degeneration starting at an early age, most patients are

still young (<55 years) and therefore surgery is postponed as long as possible. In severe ankle osteoarthritis (another form of joint degeneration) joint distraction appeared a good surgical alternative to postpone an ankle arthrodesis for many years. This treatment might also be effective for haemophilic ankle arthropathy (HAA) with the advantage of preservation of the original joint. Recently three cases from clinical practice evaluated in retrospect 2, 3, and 4 years after treatment, demonstrated good clinical and structural efficacy.

Study objective

This study is designed to gather prospective data on a) the clinical effectiveness, b) the tissue structure changes, and c) the short term costs of ankle joint distraction (AJD) in 10 patients with HAA during 10 years follow-up.

Study design

This study is a prospective interventional pilot study with 3 years follow-up. Haemophilia patients with severe complaints of ankle arthropathy in the talocrural joint, insufficiently responding to analgetics and conservative treatment, and leading to functional limitations are included. Ankle joint distraction during 10 weeks is performed. Changes in symptoms are evaluated at 6 and 12 months post-surgery and thereafter yearly up to 3 years, and at 6 and 10 years post-surgery.

Intervention

All ten patients included will be treated by ankle joint distraction during ten weeks. An external frame will generate 5 mm distraction of the joint.

Study burden and risks

There is a direct benefit for the patients because good clinical benefit is expected based on 3 cases in haemophilia and experience in patients with ankle osteoarthritis. Preservation of the original joint for several years, thus delaying the indicated joint fusion, is expected. Haemophilia patients with arthropathy visit the Van Creveldkliniek regularly. For this study, patients will visit the outpatient clinic with a comparable frequency as after a joint fusion. Because of the study at baseline (twice), 6 months, 1, 2, 3, 6 and 10 years several questionnaires have to be filled in and physical tests performed. Moreover, three and ten years after surgery an MRI is made solely for study related purposes. Additionally, 10ml of blood and 5 ml of urine are collected at all time points.
There is a risk due to the treatment and due to study related activities. However, this risks associated with participation is considered minimal, based

on the experience with the 3 cases. The distraction frame will be applied under general anaesthesia and after infusion of clotting factor concentrate. The risk of pin tract infection or bleeding does exist, but both can be treated effectively with antibiotics or clotting factor infusion respectively. After 10 weeks, the distraction frame will be removed, requiring general anaesthesia and a bolus injection with clotting factor. Moreover, there is a negligible risk due to x-ray radiation, and a small risk related to blood sampling.
The final outcome of the study will contribute to further development and positioning of AJD in the treatment of haemophilic ankle arthropathy, which may be of benefit to patients in the future and enable them to participate in their society optimally.

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

Patients with haemophilia A or B and severe complaints of ankle arthropathy in the upper ankle (talocrural) joint, insufficiently responding to analgetics and conservative treatment, and leading to functional limitations
Age >= 18 years and <= 55 years

Exclusion criteria

Contra-indications for surgery in general according to standard clinical practice protocol.
Complaints of the ankle due to arthropathy primarily in the lower ankle joint .
Psychological inabilities making it impossible to wear a distraction frame for 10 weeks or difficulty to instruct.
Contra-indications for MRI examination according to standard clinical practice protocol.
Bone-to-bone contact in the joint (absence of any joint space on X-ray)
Inflammatory or rheumatoid arthritis in the affected ankle present or in history

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-08-2013
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Ilizarov distraction frame
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	19-06-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	29-07-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-01-2019
Application type:	Amendment
Review commission:	METC NedMec

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	NL44229.041.13