Prospective study comparing open versus arthroscopic subtalar arthrodesis

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In this study the primary objective is to measure the complication rate after open or after arthroscopic arthrodesis of the subtalar joint. Secondary outcome measures comprise pain, function and patient satisfaction.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON45062

Source
ToetsingOnline

Brief title
Open versus arthroscopic subtalar arthrodesis

Condition

- Joint disorders

Synonym
degenerative arthritis, degenerative joint disease

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Arthroscopic arthrodesis, Open arthrodesis, Osteoarthritis, Subtalar joint

Outcome measures

Primary outcome

The main study parameter is the early complication rate after surgery. These early complications consist of wound healing disturbance caused by necrosis of the skin, superficial wound infection, deep wound infection, nerve damage caused by the skin incision, and tendon lacerations caused by the skin incision.

Secondary outcome

Secondary study parameters are the number of late complications (>=6 weeks), patient satisfaction, pain and function after arthrodesis. Apart from number of late complications, these parameters will be measured: preoperatively (excluding satisfaction), and after 3,6,12 months after surgery.

Study description

Background summary

Open subtalar arthrodesis is a reliable surgical technique to treat painful osteoarthritis of the subtalar joint when conservative treatment is not successful. The arthroscopic technique was introduced to reduce complications and increase healing rate after subtalar arthrodesis. Many retrospective studies have described good results after open subtalar arthrodesis and various prospective studies have described excellent results after arthroscopic subtalar arthrodesis. However, a prospective randomized study to compare the two techniques has to the best of our knowledge not been performed.

Study objective

In this study the primary objective is to measure the complication rate after

open or after arthroscopic arthrodesis of the subtalar joint. Secondary outcome measures comprise pain, function and patient satisfaction.

Study design

The study is an open randomized, prospective, one year follow-up trial.
Patients are randomly allocated to one of the two treatment groups (open or closed surgery). Due to the nature of the surgery both the subjects and the orthopedic surgeons cannot be blinded.
Measurement points (coinciding with regular practice) are: preoperative, and after 3,6,12 months.

Intervention

Open arthrodesis
Open arthrodesis is a surgical procedure of the foot where an incision is made on the lateral side of the foot to gain access to the subtalar joint. The cartilage is removed as well as a layer of 2 mm of subchondral bone in order to create a decorticated, bleeding surface. Two 7.3 mm screws are inserted to compress the bone of the talus and the calcaneus so consolidation can occur.

Arthroscopic arthrodesis
The arthroscopic technique uses two or three stab incisions around the hindfoot. Similar to the open technique, a decorticated surface is created after which the bone is compressed with 7.3 mm screws.

Study burden and risks

For the patients who will be selected from the waiting list at St. Maartenskliniek Nijmegen and already had a pre-operative visit an additional baseline visit will be planned to sign informed consent and fill in questionnaires. In Nijmegen, the post-op visit at 12 months is not part of standard care and is therefore extra for the study. In Nijmegen the total amount of extra time that patients spend on this study is 3.5 hours.

The risks associated with the open and arthroscopic techniques are not different from when the patients do not participate in the study.

Contacts

Public
Sint Maartenskliniek

Hengstdal 3

Ubbergen 6574 NA
NL
Scientific
Sint Maartenskliniek

Hengstdal 3
Ubbergen 6574 NA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Isolated subtalar osteoarthritis
2. Diagnosis primary osteoarthritis or posttraumic osteoarthritis
3. 6 Months duration of symptoms
4. Age 18-80y
5. Less than 15 degrees valgus or 5 degrees varus of the subtalar joint

Exclusion criteria

1. Previous surgery of the subtalar joint
2. Osteonecrosis.
3. Rheumatoid arthritis, Complex Regional Pain Syndrom, neurological impairment

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-08-2013
Enrollment:	52
Type:	Actual

Ethics review

Approved WMO Date:	08-07-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-02-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-05-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL44790.048.13