AS: Ankle Spacer

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26265

Source
Nationaal Trial Register

Brief title
AS

Health condition

osteochondral defects of the talus

Sponsors and support

Primary sponsor: Academic Medical Centre (Investigator-initiated trial)
Source(s) of monetary or material Support: Arthrex

Intervention

Outcome measures

Primary outcome

The primary study parameter is the measurement of the NRS pain during walking/normal weight-bearing.

Secondary outcome

Other outcome measures will include pain evaluation using the NRS pain at rest and during stair climbing, the AOFAS, FAOS, and SF-36 physical and mental component scale. Range of

Motion (ROM) will also be registered in degrees of dorsi- and plantarflexion and will be measured using a goniometer Other study parameters that will be recorded are demographic data (sex, age, etc.) and also radiographic evaluations to evaluate loosening and subsidence (radiographs). Complications, implant survivorship (revision rate), operation time, adverse events, and length of hospital stay will also be recorded.

Study description

Background summary

By means of the Ankle Spacer patients will be implanted, the clinical and radiological results of which will be prospectively recorded and analyzed at different points in time.

Study objective

Despite the fact that no clinical trials have been published on this specific implant, it is hypothesized that the 5-year postoperative clinical outcomes concerning pain and prosthesis survival will be considered good.

Study design

pre-operatively

1 day postoperatively

2 weeks posoperatively

6 weeks postoperatively

3 months postoperatively

6 months postoperatively

1 year postoperatively

3 years postoperatively

4 years postoperatively

5 years postoperatively

Intervention

All included patients will be treated by means of surgical implantation of the Ankle Spacer

prosthesis in an open manner replacing the talar side of the tibiotalar joint.

Contacts

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Eligibility criteria

Inclusion criteria

-age ranging from 18 to 80 years

-talar osteochondral defect (multiple degenerative talar cysts present, and/or prior failed surgical treatment and/or multiple defects and/or large (>15mm))

-willing to receive surgical implantation of the Ankle Spacer

-has been informed of the nature of the study and provided written consent

-The subject and treating physician agree that the subject will return for all required post-procedure follow-up visits

-failed previous conservative treatment

-complaints for at least 6 months

Exclusion criteria

-severe ankle malalignement.(> 5° varus/valgus).

-fracture < 6 months - tendinitis - diabetes mellitus / reumathoid arthritis

-advanced osteoporosis

-grade two or higher (Kellgren-Lawrence-Score) ankle joint degeneration on the tibia side.

-any ankle deformation that does not allow proper rasping of the cartilage and/or proper seating of the desired sized implant, as described in the surgical technique.

-blood supply limitations and previous infections, which may retard healing.

-foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.

-active infection or blood supply limitations.

-conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period, including severe neuro-arthropathy.

-pathological conditions, such as insufficient quantity or quality of bone (e.g., cystic changes or severe osteopenia), which may compromise implant fixation.

-currently participating in an investigational drug or another device study that clinically interferes with the current study endpoints.

-Inability to be brought back to the surgery site for long term follow-up evaluations or the subject is unwilling to fill out the appropriate evaluation forms

-adiposity grade I (BMI > 30 kg/m2)

Study design

Design

Study type:	Interventional

Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 44464
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6477
NTR-old	NTR6664
CCMO	NL62466.018.17
OMON	NL-OMON44464

Study results

Summary results

Up to now, there have no clinical studies been published with regards to the Ankle Spacer.