AS: Ankle Spacer

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26265

Bron
Nationaal Trial Register

Verkorte titel
AS

Aandoening

osteochondral defects of the talus

Ondersteuning

Primaire sponsor: Academic Medical Centre (Investigator-initiated trial)
Overige ondersteuning: Arthrex

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel

Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2017
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44464
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

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