

Total contact versus Total contact Softcast in treatment neuropathic plantar ulcers.

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A TCS is comparable to TCC and an effective treatment in neuropathic forefoot ulcer,

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

Samenvatting

ID

NL-OMON29630

Bron

NTR

Aandoening

Diabetic foot, forefoot ulcers, Total Contact Cast , Total Contact Softcast, offloading.
Diabetische Voet, voorvoet ulcus,

Ondersteuning

Primaire sponsor: UMCG Groningen

Hanzeplein 1

9700 RB Groningen

Overige ondersteuning: geen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Results of ulcer-healing equally well for TCS, as compared to TCC? When looking AT THE PERCENTAGE OF ULCER-HEALING AT 12 WEEKS FOLLOW UP.

Toelichting onderzoek

Achtergrond van het onderzoek

A Total Contact Softcast (TCS) is a new alternative treatment for patients with a forefoot ulcer.

An increasing number of Hospitals in the Netherlands use a TCS or the Total Contact Cast (TCC):

the golden standard for off-loading. Patients have a better comfort in a TCS instead of a TCC, resulting in an easier walking pattern. Cast technicians observe adequate healing of the wounds.

A comparison between both techniques was never made (to our knowledge). A TCS relieves multiple possible causes prohibiting mobilization. It may shorten the treatment duration and increase the quality of life.

The impact of excessive pressure on the sole of the foot in the pathogenesis of neuropathic plantar ulcers, is well established. It is also known that complete relief of pressure from the ulcerated area is the key to effective healing. A non-removable Total Contact Cast is the golden

standard for off-loading ulcers located at the forefoot or midfoot. Patients walk for weeks or several months with a TCC: After 12 weeks resulting in 90% healing of the patients' wounds.

This non-removable knee-high device, including ankle joint immobilization, reduces the activity

level with a potential risk of falls and knee or hip complaints due a provoked asymmetry in walking. Early discontinuation because of inconvenience of the TCC was seen in 21% of the patients. The use of a TCC is contraindicated, in patients with infection or critical ischemia.

A relative contraindication is found in elderly, patients with visual or equilibrium problems, and

patients with a contra lateral foot ulcer or varicose veins. Other reasons for discontinuation are

pressure points and joint problems in 7% of the patients. Also ankle stiffness and lower back

pain

disturb the walking pattern.

In a Total Contact Softcast the ankle is wrapped in a semi-rigid stretch bandage allowing movement of the ankle joint. The sole is constructed of a rigid cast. This allows a normal walking

pattern combined with off-loading of pressure points of the wounds. The World Health Organization (WHO) defines disability as one of the problems an individual may experience in functioning. This may be positively influenced by the accomplishment of a physically active lifestyle with a semi-rigid cast: A TCS.

Doel van het onderzoek

A TCS is comparable to TCC and an effective treatment in neuropathic forefoot ulcer,

Onderzoeksopzet

patients visit the outpatient clinic weekly for a cast change and wound inspection by a wound nurse.

Onderzoeksproduct en/of interventie

Total Contact Cast

Contactpersonen

Publiek

Europaweg-Zuid 1

B.P. Vierhout
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

age >18 years old, mental competence and understanding of the Dutch language

Diagnosis: Neuropathic ulcers without sign of ischemia, ability to walk more than 20 meters, wound depth tissue loss grade D1 and D2 according to PEDIS I1 and I2

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

patients with a Charcot deformity, excessive edema of the lower leg, immobility (<20 meters)

an ankle brachial pressure index <0.9 and clinical signs of wound infection. (wound classification according to PEDIS Classification)

Onderzoeksopzet

Opzet

Onderzoeksmodel: Anders

Blinding:

Enkelblind

Controle:

Geneesmiddel

Deelname

Nederland

Status:

Werving nog niet gestart

(Verwachte) startdatum:

31-01-2017

Aantal proefpersonen: 76
Type: Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5978
NTR-old	NTR6142
Ander register	ABR-nummer : 61960

Resultaten