ANKLE TRIAL

Gepubliceerd: 31-12-2009 Laatst bijgewerkt: 19-03-2025

No significant difference in results of functional treatment with physical therapy including a form of external support (tape or brace) in comparison with a purely functional treatment strategy with only a physical therapy programme, without any...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21996

Bron
Nationaal Trial Register

Verkorte titel
ANKLE TRIAL

Aandoening

Acute ankle sprain
Enkelbandletsel

Ondersteuning

Primaire sponsor: fund=initiator=sponsor
Overige ondersteuning: COC / Leerhuis JBZ
Postbus 90153
5200 ME 's-Hertogenbosch
h.hoekstra@jbz.nl

Bauerfeind Benelux BV
Waarderveldweg 1
2031 BK Haarlem
j.p.van.ede@bauerfeind.nl

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Foot and Ankle Outcome Score (FAOS);
2. Karlsson scoring scale.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective of the ANKLE TRIAL is to differentiate between results of three types of functional treatment in a profound methodological way, with primary research question: what will be the optimal functional treatment for acute lateral ankle ligament injuries: is there any surplus value of external support devices (tape or brace) in comparison with a purely functional treatment strategy?

Doel van het onderzoek

No significant difference in results of functional treatment with physical therapy including a form of external support (tape or brace) in comparison with a purely functional treatment strategy with only a physical therapy programme, without any external support device.

Onderzoeksopzet

1. Inclusion: within 24 hours after ankle sprain;

2. After 5-7 days;

3. After 6 weeks;

4. After 6 months;

5. After 1 year.

Onderzoeksproduct en/of interventie

1. Pressure bandage and tape, during 2 x 2 weeks;

2. Pressure bandage and brace (AirLoc®, Bauerfeind), during 4 weeks;

3. No way of external support at all.

Besides all groups will receive a scheme with ankle exercises to improve balance, coordination and strength of the surrounding muscles.

Contactpersonen

Publiek

S. Witjes
Amsterdam
The Netherlands

Wetenschappelijk

S. Witjes
Amsterdam
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. ‘Healthy’ adult patients (age above 18 years), who are able to give Informed Consent;

2. Acute (less than 24 hours), single sided and first inversion ankle trauma, whereby sprain of the lateral ankle ligaments has been occurred;

3. Sufficient knowledge of the Dutch language;

4. Living nearby the Jeroen Bosch Hospital.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Drugs- or alcohol addiction or otherwise factors that will influence compliance in a negative way;

2. Fracture, syndesmosis or medial ligament rupture, arthritis;

3. Recurrent of bilateral ankle sprain;

4. Not ambulant, wheelchair- or bed dependent patients, because of serious neurological diseases or chronically problems of the locomotor system;

5. Any co morbidity that can disturb the ‘normal’ recovery or rehabilitation tendency after ankle sprain, like ipsilateral ankle pathology, like already existing (functional) ankle instability, chondropathy, ankle fractures, connective tissue diseases (like Ehlers-Danlos) or otherwise chronic diseases.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	165
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	31-12-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36600
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2035
NTR-old	NTR2151
CCMO	NL30075.028.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36600

Resultaten

Samenvatting resultaten
N/A