Vergelijking van tape versus brace in de behandeling van een acuut lateraal enkelband letsel.

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This study is designed as a prospective randomized single blinded trial to evaluate the difference in functional outcome after treatment with tape versus semi-rigid ankle support (brace) for grade II and III acute lateral ankle ligament injuries.

Ethische beoordeling	Afgewezen
Status	Zal niet starten
Type aandoening	Pees-, ligament- en kraakbeenaandoeningen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON31464

Bron
ToetsingOnline

Verkorte titel
Tape versus brace

Aandoening

- Pees-, ligament- en kraakbeenaandoeningen

Synoniemen aandoening
enkel distorsie, enkelverstuiking

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Gelre Ziekenhuizen
Overige ondersteuning: Ministerie van OC&W,Smith&Nephew, Inc

Onderzoeksproduct en/of interventie

Trefwoord: Conservatieve behandeling, Enkelband letsel, Kosteneffectivetiet, Tape / brace

Uitkomstmaten

Primaire uitkomstmaten

1. Karlsson scoring scale 37

We ask the patient to fill out a questionnaire regarding the function of the ankle joint. The score includes eight items based on a subjective evaluation of stability, pain, swelling and stiffness in relation to activities of everyday life, sports and recreational activities, running, stair climbing and working ability. The maximum score is 100 points. (Appendix B)

Excellent 90-100 points

Good 80-89 points

Fair 60-79 points

Poor <=60 points

Secundaire uitkomstmaten

2. Foot and Ankle Outcome Score. FAOS (Appendix A).34, 35

· FAOS consists of 5 subscales; Pain, other Symptoms, Function in daily living (ADL), Function in sport and recreation (Sport Rec), and foot and ankle-related Quality of Life (QOL). The last week is taken into consideration when answering the questionnaire. Standardized answer options are given (% Likert boxes) and each question gets a score from 0 to 4. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale. The result can be plotted as an outcome profile.

· FAOS content is based on the Knee injury and Osteoarthritis Outcome Score (KOOS) 34, content validity was confirmed by 213 patients with ankle instability. 35

· FAOS was developed to assess the patients* opinion about a variety of foot and ankle related problems. FAOS is patient-administered and takes about 10 minutes to fill out.

3. Return to work

· Time to return to work

· Work at level / below level / no return to work

4. Return to sports.

· Time to return to sports

· Sports at level / below level /no return to sports

5. Pain

· VAS score 0-10: 0 = no pain, 10 = unbearable pain

6. Objective instability

· Objective instability of the ankle is either measured during physical examination using the TTT (>=90 or >= 30 difference with uninjured ankle) The talar tilt test or inversion stress test is performed in the same position and a varus force is applied to the heel. In maximal dorsiflexion the contribution of the subtalar joint is minimised and the calcaneo-fibular ligament is taut. This is a test predominantly of the calcaneo-fibular ligament. The second test is the Anterior Drawer Test (ADT). The patient sits on a bench with the legs hanging downwards. The knee joint is flexed and the foot held in 150 plantar flexion. First the healthy ankle is examined. Examination is performed

according to van Dijk. 38 The examiner assigned one of the four predetermined numbers to each examined ankle joint, based on the estimated anterior displacement of the talus relative to the tibia.

o 0 = 0-2mm, 1 = 3-5mm, 2 = 6-10mm and 3 = 11-15mm.

· Because the manual ADT is of a subjective nature we measure the instability with the dynamic anterior ankle tester (DAAT). 39 The principle of the test is to apply a force impulse tot the calcaneus, within the muscle reflex time, and to measure anterior-posterior translation and mediolateral rotation. The highest and the lowest score were discarded and the mean of the three remaining scores counted as the result of the test.

7. Range of motion

· Degrees maximum dorsiflexion to plantarflexion

· Limited: yes / no (>5 degrees, compared to healthy side)

8. Recurrent inversion injury

· Yes/no

· Number of sprains per month

9. Complications / Adverse events

· Any event leading to discontinuation of study participation and temporary or permanent physical damage due to the treatment under investigation (Local skin irritations (contact dermatitis and folliculitis), sensory deficit, stiffness, muscle atrophy)

· Yes / no

· Total number of complications per patient and per group

10. Tegner activity level (modified, Appendix C) 33

· Mean per group

11. EuroQol

The EuroQol (EQ5D) is a health related quality of life instrument that provides a single index of an individual*s quality of life. It consists of 5 dimensions resulting in 243 possible health states.

12. Preference of the patient for brace or tape treatment.

· (Tape/Brace)

13. Compliance

· How many days did you not wear the brace?

· Tape compliance is always 100%

14.Economic evaluation

. The main objective of the economic evaluation is to assess the cost effectiveness and cost-utility of brace and tape therapy of acute lateral ankle ligament injury. The economic evaluation will be performed from a societal perspective, implying that all relevant costs, such as costs of the intervention, other health care costs, patient and family costs and costs of production loss will be used as economic indicators

Toelichting onderzoek

Achtergrond van het onderzoek

Injury to the anterolateral ligament complex of the ankle, or ankle sprain, is a common problem in acute care practice. The incidence is estimated at 1 per 10.000 people per day and ankle sprains form about a quarter of all sports injuries. Some sports (basketball, soccer and volleyball) have a particularly high incidence of ankle injuries.Ankle sprains may lead to persisting symptoms in 30-40% of all patients.

There is no high level evidence, with regard to clinical or financial outcome, for the superiority of taping or bracing. According to the Cochrane Systematic Review about different functional treatment options (including taping and bracing) for acute ankle ligament injuries *there is no medical or socio-economic evidence that taping is preferable to bracing or oppositely*.

Doel van het onderzoek

This study is designed as a prospective randomized single blinded trial to evaluate the difference in functional outcome after treatment with tape versus semi-rigid ankle support (brace) for grade II and III acute lateral ankle ligament injuries.

Onderzoeksopzet

Of potential patients at the emergency department, injury and general history will be obtained and the lower extremity will be examined. The presence or absence of an ankle fracture will initially be assessed according to the Ottawa ankle rules. 36 If a fracture can not be excluded, X-rays of the ankle will be made.
When the diagnosis *acute inversion ankle ligament injury* is made, RICE-therapy (Rest, Ice application, Compression with a pressure bandage and Elevation) will be started and patients will be advised not to bear weight on the injured leg until the first visit. An appointment at the outpatient clinic for delayed physical examination after 4-6 days will be made.21 Written patient information and an informed consent form will be administered.
Patients qualifying for grade II or III ligament injury at delayed physical examination will be asked to participate in the study. After signed informed consent is obtained, patients will be included in the study and randomized into two groups. Randomization will be performed by computer. Blinding of patients and observer is not possible, but analysis of the data will be in a blinded fashion.

Onderzoeksproduct en/of interventie

Group 1 will be treated with adhesive non-elastic tape for six weeks. Group 2 will be treated with a semi-rigid brace for six weeks. Use and application will be explained by the researcher using a standardised protocol. Apart from the investigated treatment, patients will undergo the same rehabilitation program: active range of motion training, weight bearing as tolerated, and use of crutches until the pain subsides and full weight bearing is reached. The use of additional treatment (ultrasound, cryotherapy, laser, homeopathy and physiotherapy) will not be allowed. Analgesics are allowed, with the exclusion of non-steroidal anti-inflammatory drugs (NSAID>s).

Inschatting van belasting en risico

The purpose and consequently the benefit of our study is to determine the optimal non-surgical treatment for acute lateral ankle ligament injury, tape, brace or lace-up brace treatment. To our knowledge there are no potential risks for the included patients, as both treatments have been described as being safe with little chance of complications. Only for tape, skin local irritations, such as contact dermatitis and folliculitis, were reported.19 These complications will resolve without any problem and can be reduced by practising proper technique. The tape bandage can be too tight.

Contactpersonen

Publiek

Gelre Ziekenhuizen

Albert Schweitzerlaan
7300 DS Apeldoorn
Nederland

Wetenschappelijk

Gelre Ziekenhuizen

Albert Schweitzerlaan
7300 DS Apeldoorn
Nederland

Locaties

Landen waar het onderzoek wordt uitgevoerd

Netherlands

Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patienten ouder dan 18 jaar
Graad II en III enkeldistorsies

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

patienten met chronische enkel instabiliteit
met een fractuur op de rontgen opname van de enkel
ander traumata of beperkingen aan hetzefde lidmaat
alcohol abusus, majeure psychiatrische of neurlogische aandoeningen
bilaterale enkeldistorsies
chirurgie van de laterale enkelbanden in voorgeschiedenis
huidziekten waardoor taping niet mogelijk is
patienten die geen informed consent kunnen geven
patienten die de vragenlijst niet kunnen invullen
neuromusculaire aandoeningen van het onderste extremiteit
actieve rheumatoide arthritis
stoornissen in het looppatroon
complicaties of bijwerkingen van de behandeling

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep
Doel:	Behandeling / therapie

Deelname

Nederland
Status: Zal niet starten

Aantal proefpersonen:	106
Type:	Verwachte startdatum

In onderzoek gebruikte producten en hulpmiddelen

Generieke naam:	tape
Registratie:	Geregistreerd voor gebruik zoals toegepast in onderzoek

Ethische beoordeling

Afgewezen

Datum:	26-02-2008
Soort:	Eerste indiening
Toetsingscommissie:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL18120.041.08