Tape versus semi-rigid ankle support in the treatment of acute lateral ankle ligament injury.

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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.

Ethical review	Not approved
Status	Will not start
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON31464

Source
ToetsingOnline

Brief title
Tape versus brace

Condition

- Tendon, ligament and cartilage disorders

Synonym
ankle sprain, lateral enkel ligament injury

Research involving
Human

Sponsors and support

Primary sponsor: Gelre Ziekenhuizen
Source(s) of monetary or material Support: Ministerie van OC&W,Smith&Nephew, Inc

Intervention

Keyword: Ankle ligament injuries, cost-effectiveness, non-surgical treatment, tape / brace

Outcome measures

Primary outcome

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

Secondary outcome

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

Study description

Background summary

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*.

Study objective

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.

Study design

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.

Intervention

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).

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients over 18 years
Grade II or III ankle sprains

Presentation < 72 hours after the acute injury

Exclusion criteria

Patients with a history of chronic instability
Who had a fracture on X-ray investigation
Other injuries or disabilities on the same limb
Alcoholism, serious psychiatric and neurological illness
Patients with bilaterally sprained ankles
Patients with previous surgery on the lateral ankle ligaments
Skin diseases where taping is not practicable
Patients who are unable to give informed consent
Patients who are unable to fill out questionnaires
Neuromuscular disorders of the lower extremities
Active rheumatoid arthritis
Gait disturbances
Complication/Adverse event

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	106
Type:	Anticipated

Medical products/devices used

Generic name:	tape

Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	26-02-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL18120.041.08