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Effectiveness of treatment with brace versus tape in acute lateral ankle sprains

Submission date
12/10/2011

Recruitment status
No longer recruiting

Registration date
03/01/2012

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Ankle sprains are the most frequently reported sports injuries often leading to pain and other impairments including chronic physical limitations and impingement. Another frequently regularly reported problem is the recurrence of an ankle sprain. The risk of re-spraining within a period of 3 years after the initial ankle sprain was reported to range from 3 to 34%. Since the 1990s, functional treatment of ankle sprains is highly recommended. Nowadays, the regular treatment of an ankle sprain includes ankle taping, while the use of an ankle brace is conventional to prevent re-injuries is conventional.
The purpose of this study is to investigate the effect of a 4-week treatment with an ankle brace (soft brace) compared to the treatment with an ankle tape on recurrent sprain and residual problems within one year in patients with an acute lateral ankle sprain.

Who can participate?
If you are aged over 18 and diagnosed with an acute lateral ankle sprain caused by an inversion trauma, you can participate in this study.

What does the study involve?
When you decide to participate in this study you are treated with an ankle brace or ankle tape for four weeks. A sports physician conducts the initial measurements (baseline) consisting of an anamnesis and a physical exam during which the ankle is examined for swelling, discoloration by hematoma, limited dorsiflexion and tenderness at baseline. Several tests are performed to measure passive and active ankle stability. After the baseline measurements, at week 5, 9, 13, 26 and 39 post-trauma, you have to fill in online questionnaires asking about re-injuries and residual complaints. After 52 weeks a final assessment by a sports physician takes place.

What are the possible benefits and risks of participating?
Ankle brace treatment and ankle tape treatment can result in skin irritations or dermatitis. If you are familiar with this hyper sensitiveness of the skin, preventive measures can be taken in advance.

Where is the study run from?
The study was organised by the Department of Revalidation, Nursing Science and Sport of the

University Medical Centre Utrecht (Netherlands). Twenty GPs, nine physiotherapy practices and two emergency departments in the region of Utrecht recruited patients for this study.

When is the study starting en how long is it expected to run for?
The study was open for patients between May 2006 and October 2009. Follow-up examinations continued until one year after inclusion. The total data collection ended in November 2010.

Who is funding the study?
This study was funded by NEA International, manufacturer of the ankle brace type Push med Ankle Brace.

Who is the main contact?
Mrs Ingrid van de Port, PhD (senior researcher)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Effectiveness of a 4 week treatment with ankle brace versus ankle tape on recurrent sprain and residual problems within one year in patients with acute lateral ankle sprains

Study objectives
The treatment of acute lateral ankle sprains with an ankle brace is more effective than the treatment with ankle tape

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Medical Centre Utrecht Ethics Committee, 29/11/2005, ref: 05/153

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Dr Ingrid van de Port (iport@umcutrecht.nl) to request a patient information sheet

Health condition(s) or problem(s) studied
Acute lateral ankle sprain

Interventions
The intervention group received instructions from the sports physician about how to use and fix the Push Med ankle brace, which is a soft brace and based on the principle of the functional tape bandage. The patients were instructed to wear the ankle brace for four weeks, except when taking a shower. The control group received ankle tape for four weeks. The tape bandage was applied by the GP, assistant, physiotherapist or the plaster technician. The tape technique was applied as usual. A new tape was provided at a maximum of two weeks after the first application by one of the mentioned persons.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Risk for re-injury based on the amount of patients reporting re-injuries within one year

Secondary outcome measures
1. Residual symptoms (objective and subjective)
1.1. The objective residual symptoms were swelling (yes/no), functional outcome, passive and active stability
1.2. The subjective residual symptom was pain
2. Dorsiflexion of the ankles was measured to determined functional outcome. Patients could have limited dorsiflexion in the injured ankle compared to the healthy ankle, no limitation in dorsiflexion, or better dorsiflexion than the healthy ankle.
3. Passive stability was measured with dynamic anterior ankle tester. The passive stability of both ankles could be equal, the passive stability of the injured ankle could be worse than the healthy ankle, or the passive stability of the healthy ankle could be worse than the injured ankle.
4. Four one leg stance tests with increasing difficulty with increasing difficulty were applied to measure active stability. The first one leg stance test was conducted with eyes open, the second with eyes closed, the third with eyes closed and knee in 45 degrees dorsiflexion, and the last, and most difficult, with eyes closed, knee in 45 degrees dorsiflexion and standing on the forefoot. Both legs were tested. Being able to stand on one leg for 15 seconds was classified as having accomplished a one lag stance test.
5. Pain consisted of four components associated to different activities, namely walking, running, turning and jumping. Patients were classified as having pain when they reported they had pain during at least one of these activities.

Overall study start date
01/05/2006

Completion date
18/11/2009

Eligibility

Key inclusion criteria
1. At least 18 years old
2. Diagnosed with an acute lateral ankle sprain caused by an inversion trauma
3. Had to visit one of the participating practices or emergency departments within 14 days after the inversion trauma

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

200

Total final enrolment
157

Key exclusion criteria
1. Patients who sustained an eversion trauma, multiple trauma or complicated trauma (including cartilage injuries, fractures and dislocation)
2. Had a history of ankle surgery
3. Mentally incompetent patients

Date of first enrolment
01/05/2006

Date of final enrolment
01/10/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Rudolf Magnus Institute of Neuroscience
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
University Medical Center Utrect (Netherlands)

Sponsor details
PO Box 85500
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Sponsor type
Hospital/treatment centre

Website
http://www.umcutrecht.nl/

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Industry

Funder Name
NEA International [manufacturer of Push Brace] (Netherlands)

Funder Name
University Medical Centre Utrecht (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/04/2015	17/12/2020	Yes	No