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Tape versus brace treatment of ankle distortion

Submission date	Recruitment status	[ ] Prospectively registered
21/03/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/07/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/07/2011	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL20031.068.07

Study information

Scientific Title

Prospective randomized controlled trial comparing tape versus semi-rigid brace treatment of patients with grade II and III ankle ligament rupture

Acronym
TAPELOC

Study objectives
Treatment of lateral ankle sprain with a semi-rigid brace leads to less local complications and more patient satisfaction than treatment with tape. Reduction in complications will improve patient satisfaction with the treatment method and this will improve functional outcome by enhancing compliance with the treatment method used.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Maastricht University Medical Center Ethical Committee, 03 December 2007, ref: MEC07-2-094

Study design
Prospective randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Ankle distortion, ankle ligament rupture

Interventions
1. Tape treatment: after randomisation tape immobilisation is started 5-8 days after initial treatment with immobilisation using bandage
2. Taping is performed by a select group of experienced and skilled healthcare professionals of the outpatient clinic
3. The tape consists of three layers
4. The first layer is a latex free, adhesive, bandage to protect the skin (Coban, 3M)
5. The second layer consists of 2.5cm non-elastic strapping tape (Leukotape, Beiersdorff) used for support
6. The third layer consists of Elastoplasts 6cm broad, elastic used for fixation of the second layer (BDF, Beiersdorf)

7. This taping is applied twice with two weeks interval
8. The other group is treated with a semi-rigid brace (AirLoc ® Bauerfeind, Zeulenroda, Germany)
9. After instructions to the patient how to reapply the brace, revision of these instructions is made after 2 weeks
10. Total duration of both treatment is 4 weeks
11. Follow-up duration is 12 weeks after randomization

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Patient satisfaction is assessed by verbal rating scale: poor (5), moderate (4), sufficient (3), good (2) and excellent (1) both at 2 and 4 weeks after start of the study treatment
2. Level of pain is evaluated using the visual analogue scale at baseline, 2, 4, 8 and 12 weeks
3. Ankle joint function is assessed using the validated Karlsson scoring scale at 2, 4, 8 and 12 weeks after start of the study treatment
4. Range of motion is measured using an electronic goniometer at 2, 4, 8 and 12 weeks after start of the study treatment

Secondary outcome measures
Any complications of the treatments

Overall study start date
01/01/2008

Completion date
31/12/2011

Eligibility

Key inclusion criteria
Patients were included if they sustained a grade II or III ankle sprain (significant damage to lateral ligaments defined by the presence of a lateral hematoma and tenderness at the anterior lateral ligament without or with instability) and were presented in the outpatient clinic within 5-7 days.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Fracture
2. Age was under 16 or over 55 years
3. If they had experienced a previous ankle sprain or fracture
4. If they sustained swelling that makes tape treatment impossible

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Surgery
Maastricht
Netherlands
6226 BV

Sponsor information

Organisation
Maastricht University Medical Center (Netherlabnds)

Sponsor details
c/o Prof. Peter R.G. Brink
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Sponsor type
University/education

Website
http://www.maastrichtuniversity.nl/

ROR
https://ror.org/02d9ce178

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Maastricht University Medical Center (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