Ankle treatment after injuries of the ankle ligaments

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON32452

Source
ToetsingOnline

Brief title
ANKLE TRIAL (= ANKLE TReatment after Injuries of the Ankle Ligaments)

Condition

- Tendon, ligament and cartilage disorders

Synonym
ankle distorsion, ankle sprain

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Bauerfeind,Firma Bauerfeind (verstrekking braces);verder geen extra kosten

Intervention

Keyword: ankle injuries, functional treatment strategies, lateral ligaments, sprains

Outcome measures

Primary outcome

VAS - pain score

Number of days to return to work and sports

Presence of objective and subjective instability

Number of recurrent injuries

VAS - patient satisfaction

Secondary outcome

Side effects

Costs

Study description

Background summary

Inversion ankle sprains are very common problems in present health care. In spite of a lot of published reports concerning treatment of ankle injuries, still no definite conclusions concerning the most optimal treatment strategy can be drawn. Current evidence supports the view that a functional treatment strategy is preferable, but insufficient data is present to prove a surplus value of the addition of external support. Possible described disadvantages of external support devices are just acceptable when benefits of this treatments have been proven. Hypothesis of our study is that a functional therapy supplemented by external ankle support will not show statistically significant better results than a purely functional treatment strategy in management of acute ankle sprains.

Study objective

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? Furthermore, we want to investigate the influence of gravity of the ankle sprain or degree of sports intensivity in determining which therapy is to prefer.

Study design

Prospective, open randomised controlled trial

Intervention

After inclusion patients are randomised in 3 treatment groups, which will all been treated functionally (physical therapy) next to:
1 - intervention group: pressure bandage and tape
2 - intervention group: pressure bandage and brace (AirLoc®, Bauerfeind)
3 - control group: no way of external support at all

Study burden and risks

Patients are proposed to several questions and will undergo short physical examination in the time of inclusion (scoring moment 1), after 5 to 7 days and after 6 weeks (respectively scoring moment 2 and 3). Furthermore they will the be phoned up for an interview after 6 months and possibly they will be asked for anamnesis and examination after 1 year. Estimated extended burden in comparison of current standard treatment and follow up: 1 or 2 extra hospital visits, depending on the randomised treatment (change of tape requires an extra hospital visit). In our opinion the risks for the participating patients will be small, because we estimate that there do not exist big result differences between the three investigated treatment strategies.

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

- acute injury to the lateral ligament complex
- single sided and first trauma of the ankle, by what injury of the lateral ligaments has occured

Exclusion criteria

- alternative diagnoses, like fractures (somewhere in the injured lower limb), rupture of the syndesmosis or medial ligaments or arthritis
- recurrent ankle sprains
- double sided sprains (both left and right ankle) or other injuries at the other extremity
- comorbidities otherwise which could disturb the normal healing- and rehabilitation tendency of the ankle sprain

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2009
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	AirLoc / ankle support;CE: 93/42/EEC
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	18-12-2008
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL24630.028.08