ANKLE TRIAL

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21996

Source
Nationaal Trial Register

Brief title
ANKLE TRIAL

Health condition

Acute ankle sprain
Enkelbandletsel

Sponsors and support

Primary sponsor: fund=initiator=sponsor
Source(s) of monetary or material Support: COC / Leerhuis JBZ
Postbus 90153
5200 ME 's-Hertogenbosch
h.hoekstra@jbz.nl

Bauerfeind Benelux BV
Waarderveldweg 1
2031 BK Haarlem
j.p.van.ede@bauerfeind.nl

Intervention

Outcome measures

Primary outcome

1. Foot and Ankle Outcome Score (FAOS);

2. Karlsson scoring scale.

Secondary outcome

1. FAOS subscales: pain, other symptoms, ADL, sport en recreation, quality of life;

2. Number of recurrent ankle injuries;

3. VAS satisfaction;

4. Side effects.

Study description

Background summary

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?

Study objective

No significant difference in results of functional treatment with physical therapy including a form of external support (tape or brace) in comparison with a purely functional treatment strategy with only a physical therapy programme, without any external support device.

Study design

1. Inclusion: within 24 hours after ankle sprain;

2. After 5-7 days;

3. After 6 weeks;

4. After 6 months;

5. After 1 year.

Intervention

1. Pressure bandage and tape, during 2 x 2 weeks;

2. Pressure bandage and brace (AirLoc®, Bauerfeind), during 4 weeks;

3. No way of external support at all.

Besides all groups will receive a scheme with ankle exercises to improve balance, coordination and strength of the surrounding muscles.

Contacts

Public
S. Witjes
Amsterdam
The Netherlands
Scientific
S. Witjes
Amsterdam
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Eligibility criteria

Inclusion criteria

1. ‘Healthy’ adult patients (age above 18 years), who are able to give Informed Consent;

2. Acute (less than 24 hours), single sided and first inversion ankle trauma, whereby sprain of the lateral ankle ligaments has been occurred;

3. Sufficient knowledge of the Dutch language;

4. Living nearby the Jeroen Bosch Hospital.

Exclusion criteria

1. Drugs- or alcohol addiction or otherwise factors that will influence compliance in a negative way;

2. Fracture, syndesmosis or medial ligament rupture, arthritis;

3. Recurrent of bilateral ankle sprain;

4. Not ambulant, wheelchair- or bed dependent patients, because of serious neurological diseases or chronically problems of the locomotor system;

5. Any co morbidity that can disturb the ‘normal’ recovery or rehabilitation tendency after ankle sprain, like ipsilateral ankle pathology, like already existing (functional) ankle instability, chondropathy, ankle fractures, connective tissue diseases (like Ehlers-Danlos) or otherwise chronic diseases.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	165
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-12-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36600
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2035
NTR-old	NTR2151
CCMO	NL30075.028.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36600

Study results

Summary results
N/A