Braces versus proprioceptive exercise for the secondary prevention of ankle sprains; a randomised controlled trial and cost-effectiveness evaluation.

Published: 25-03-2010
Last updated: 03-05-2024

To evaluate the cost-effectiveness the current ruling widespread Royal Dutch Physiotherapy Association guideline, in which the combined use of braces and proprioceptive training after ankle sprain treatment is advocated (usual care), against the use...

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

Summary

ID

NL-OMON34759

Source
ToetsingOnline

Brief title
ABBA 3

Condition

- Tendon, ligament and cartilage disorders

Synonym
acute lateral ankle ligament injury, ankle sprain

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: ankle sprain, brace, neuromuscular training, prevention

Outcome measures

Primary outcome

The primary outcome measures will be incidence of ankle sprain recurrences. An economic evaluation will determine and compare the total costs for subjects in all four trial arms, and to relate these costs to the effects of these groups.
The economic evaluation will be performed alongside the randomised controlled trial and from a societal perspective.

Secondary outcome

Secondary outcome measures include recurrence severity, residual complaints, and knowledge and attitude regarding the prevention of ankle sprain recurrences.

Study description

Background summary

Ankle sprains are the most common sports and physical activity (PA) related injury. It has been estimated that about 25% of all injuries across all sports are ankle injuries. Of all ankle injuries 85% involve the lateral ankle ligaments, i.e. acute lateral ankle sprains. There is extensive evidence that there is an up to twofold increased risk for ankle re-injury during the first year post- injury. A recent systematic review conducted by our research group, revealed that both braces as well as proprioceptive training have been proven equally effective for prevention of ankle sprains. This raises efficiency questions regarding current usual care after an ankle sprain, as secondary preventive costs can potentially be reduced simply by reducing the current content of usual care.

Study objective

To evaluate the cost-effectiveness the current ruling widespread Royal Dutch Physiotherapy Association guideline, in which the combined use of braces and proprioceptive training after ankle sprain treatment is advocated (usual care), against the use of braces and proprioceptive training as separate secondary preventive measures.

Study design

Randomised Controlled Trial

A total of 357 participants is required at baseline. All analyses will be carried out according to the intention-to-treat principle. Cox- regression analysis will be used to compare ankle recurrence risk between the intervention and control groups.

The proposed study will have a duration of 3 years and will start in January 2010. Recruitment will last 9 months until December 2010. Follow-up lasts exactly 12 months for each subject, final measurements will take place in December 2011.

Intervention

Subjects allocated to either the *usual care* or brace group will receive an Aircast A60 ankle brace. They will be strongly advised to wear this ankle brace during competition, as in the current ruling KNGF guideline. Subjects of either the *usual care* or proprioceptive group will receive a standardized eight-week proprioceptive training programme.

Study burden and risks

Participants will be asked to complete a questionnaire at baseline. Hereafter, a short retrospective follow-up questionnaire will be completed each month. In case of recurrent injury participants will complete an injury registration form as well as an cost-diary.

Next to these measurements, participants randomised to the training group are required to perform proprioctpeive exercises three times a week for a period fo eight weeks. Participants in the brace group will be asked to wear a brace during their regular sports activities.

Participants will not be at any risk. This concerns a comparative study on proven preventive measures.

Contacts

Public
Vrije Universiteit Medisch Centrum

Van der Boechorststraat 7
1081BT Amsterdam
NL
Scientific
Vrije Universiteit Medisch Centrum

Van der Boechorststraat 7
1081BT Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. sustained an acute lateral ankle ligament injury within 4 weeks before inclusion
2. are currently being (para)medically treated for that acute lateral ankle ligament injury

Exclusion criteria

Patients with an ankle fracture are excluded

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2010
Enrollment:	357
Type:	Actual

Medical products/devices used

Generic name:	Brace
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	25-03-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL31785.029.10