Diagnostics in persistent complaints after a lateral ankle sprain

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Primary goal of this study:1) To determin the percentage of structural damage caused by an ankle inversion trauma. 2) Investigate to which patient characteristics, anamnestic characteristics, physical examination and structural characteristics...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON39518

Source
ToetsingOnline

Brief title
Persistent complaints after a lateral ankle sprain

Condition

- Joint disorders

Synonym
sprain; distorsion

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW - Alledaagse Ziekten

Intervention

Keyword: ankle, diagnostics, persistent complaints, sprain

Outcome measures

Primary outcome

Persistent complaints (measured with recovery on a 7-point Likert scale; pain intensity on a 0-10 numerical rating scale; instability/feeling of instability on a 0-10 numerical rating scale)

Secondary outcome

- Structural pathology (MRI, X-ray, 0-2 score for severity, seperately for each item)

- Influence of persistent complaints on daily functioning (work, sports and daily activities 0-5 point-scale)

Study description

Background summary

Ankle sprains are the most frequent injuries to the human locomotor system. Yearly there about 600.000 new cases in the Netehrlands. About half of these cases visit their general practitioner or the emergency department of the hospital. The NHG-standard (Dutch Standard for General Practitioners) 'Ankle sprains' holds guidelines for the diagnostics and treatment. This standard also shows there is still a large number of gaps in the diagnostics and treatment of these injuries. A recent study has shown that 20-40% of the patients with a lateral ankle sprain still experiences pain after 3 months following the injury. Moreover, the general practitioner gets visited rather frequently by patients with persistent complaints. Persistent complaints like pain and instability are frequently encountered, however it is unknown which patients keep having persistent complaints despite of several interventions (see gaps NHG-standard). It is also important to gain insight in the nature of these persistent complaints or, what are the exact characteristics of these residual complaints. An enhancement of the knowledge on this subject is of great value to the general practitioner, so that they can inform their patients more

adequately and interventions and/or referrals can be adjusted to the patients needs in an earlier stage. To gain insight in patients who, despite of all kinds of interventions, still have persistent complaints it is essential to carry out a cohort study in which patients with and without persistent complaints fill-out an extensive questionnaire (anamnesis, function, recovery, patient characteristics) and undergo an extensive physical examination. Additionally, an extremity-MRI and an X-ray will be made of the ankle to identify structural abnormalities (underlying pathology) that are possibly associated with persistent complaints.

Study objective

Primary goal of this study:
1) To determin the percentage of structural damage caused by an ankle inversion trauma.

2) Investigate to which patient characteristics, anamnestic characteristics, physical examination and structural characteristics persistent complaints following a lateral ankle sprain relate.

Secondary goals:
3) If structural characteristics relate to persistent complaints: to what extent structural damage can be predicted (diagnosed) from anamnesis and physical examination.

4) To evaluate the impact of persistent complaints following a lateral ankle sprain on work, daily activities and sport participation.

5) To answer the question: What is the value of an X-ray for persistant complaints after a lateral ankle trauma and what is the correlation between the findings of the x-ray and the complaints?
6) To answer the question: What is the additional diagnostic value of an MRI compared to an X-ray for patiënts with persistant complaints after a lateral ankle trauma? Is there a complementary role of both radiological techniques?

Follow-up measurements:
7. To determint the percentage presistent complaints and re-sprains after 4 years of follow-up, as a result of a lateral ankle sprain.
8. To determine possible porgnostic factors for persistent complaints, 4-5 years after patients have visited the general practitioner with a lateral ankle sprain.

Study design

To answer question 1-4, 350 patients who visited their general practitioner 6-12 months ago with a lateral ankle sprain will be included in a cohort study.

These patients will be selected from the files of general practitioners and are contacted on behalf of the general practitioner to participate in the study.
All patients who meet the inclusion criteria will receive an extensive questionnaire with questions about persistent complaints, treatments, patient characteristics and anamnestic characteristics. Furthermore, all patients with residual complaints will be selected along with a matched control group of patients without persistent complaints (nested case-control design). These patients will additionally be invited for a standardised physical examination, X-ray and a Magnetic Resonance Imaging (MRI) scan.
After four years, al participating subjects will receive a questionnaire informing on persistent symptoms.

Study burden and risks

Patients will receive additional radiation. However, the additional radiation is small considering the location of the ankle joint, far away from vital or radiation sensitive organs. The effective dose for an x-ray in two directions is estimated at 0.002 microSv. Apart from this small additional radiation there are no other risks connected to the addition of X-rays of the ankle joint. Furthermore, the risks and burden for the patient are relatively small. The study includes a one time visit to a nearby research location, the filling out of a questionnaire, a physical examination and an MRI. In total it will cost the patient about 90 minutes. The patient will be supported throughout the entire study andcan, if wanted, get support to fill out the questionnaire. The information provided by the researchteam will probably contribute to earlier recognition and better treatment of persistent complaints following lateral ankle sprains.

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

1.) Consultation general pratitioner, minimally 6 months and maximally 12 months ago, for a ankle inversion trauma and 2.) Age 16 -65 years old

Exclusion criteria

- Familiar with systemic disorders which have a substational influence on the function of the musculoskeletal system (for example, neurological disorders such as ALS, MS and auto-immune disorders such a reumatology and psoriatric arthritis
- No knowlegde on the Dutch language in word and writing
- Contra-indication for MRI-scan

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2010
Enrollment:	206
Type:	Actual

Ethics review

Approved WMO Date:	04-03-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-06-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-02-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL30645.078.09