BOAR trial: Bernese versus Ottawa Ankle Rules. Comparison of diagnostic accuracy and reproducibility of two clinical decision rules for acute ankle/foot injuries

Published: 21-10-2013
Last updated: 24-04-2024

Compare sensitivity and specificity of both rules as well as compare the accuracy between observer groups for these rules. Also the interobserver agreement is assessed to test whether the rules are reproducible.

Ethical review	Approved WMO
Status	Pending
Health condition type	Fractures
Study type	Observational invasive

Summary

ID

NL-OMON39009

Source
ToetsingOnline

Brief title
BOAR trial (Bernese vs Ottawa Ankle Rules)

Condition

- Fractures

Synonym
ankle sprain

Research involving
Human

Sponsors and support

Primary sponsor: De Heel - Zaans Medisch Centrum
Source(s) of monetary or material Support: nauwelijks kosten;alleen van 35% extra enkelfoto's = 70 foto's

Intervention

Keyword: Bernese Ankle Rules, Diagnostic Accuracy, Ottawa ankle Rules, Reproducibility

Outcome measures

Primary outcome

Sensitivity and specificity of both observer groups compared between the two

rules

Secondary outcome

Interobserver agreement of both rules

Study description

Background summary

For ankle sprains, the Ottawa ankle rules are developed, pertaining a decision rule that accurately detects fractures, however still many x-rays need to be made to detect these fractures. Therefore, still many patients undergo unnecessary radiography. In Bern, a decision rule for the ankle has been developed that has been claimed to have a much higher specificity (91%) together with a 100% sensitivity. This would mean a large reduction in unnecessary x-rays, with less radiation, waiting time and costs as a result. However, this rule has not been validated by an independent researchgroup and therefore needs to be carefully interpreted.

Study objective

Compare sensitivity and specificity of both rules as well as compare the accuracy between observer groups for these rules. Also the interobserver agreement is assessed to test whether the rules are reproducible.

Study design

Cross sectional, interobserver trial

Study burden and risks

Extra patients undergo radiation exposure as well as prolonged ED waiting time due to the investigation

Contacts

Public
De Heel - Zaans Medisch Centrum

Koningin Julianaplein 58
Zaandam 1502DB
NL
Scientific
De Heel - Zaans Medisch Centrum

Koningin Julianaplein 58
Zaandam 1502DB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with ankle sprain
Age 18-65 yr
Presentation ED within 48 hr after trauma

Exclusion criteria

prior ankle fracture on ipsilateral side
open fractures
concomittant participation in other trial
mental or physical impairment prohibiting clinical judgment
ankle trauma as part of polytrauma

Study design

Design

Study type: Observational invasive

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2013
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-10-2013
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL43168.094.13