Trauma to Ankle and Ligaments; evaluation with UltraSound, TALUS study

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to calculate the diagnostic test accuray and by doing so to determine the value of ultrasound in ankle trauma.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Observational non invasive

Summary

ID

NL-OMON42803

Source ToetsingOnline

Brief title nvt

Condition

• Fractures

Synonym ankle fracture, fracture of the ankle

Research involving Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis **Source(s) of monetary or material Support:** geen externe financiering van echo onderzoek.

Intervention

Keyword: ankle trauma, talar crural joint affusion, ultrasound

Outcome measures

Primary outcome

diagnostic accuracy of ultrasound in ankle trauma

Secondary outcome

diagnostic accuracy of items of the Ottawa Ankle Rules in ankle trauma

Study description

Background summary

Trauma to the anklejoint is both frequently encountered and costly if not identified and treated correctly.

current diagnostic protocols describe the use of Ottawa Ankle Rules, validated for use in inversion trauma, but also used as a clinical prediction rule in all types of ankle trauma. This clinical prediction rules has high sensitivity, but poor specificity, leading to unneccesary X-ray assessments studies on ultrasound use in ankle trauma are promising and need further validation before ultrasound can be placed in diagnostic protocols. Therefore we designed a study comparing ultrasound exams with clinical prediction rules based on items of the Ottawa Ankle Rules with the X-ray exam as golden standard.

Study objective

to calculate the diagnostic test accuray and by doing so to determine the value of ultrasound in ankle trauma.

Study design

Cross sectional design comparing two diagnostic tools; ultrasound and clinical prediction rule.

Intervention

see protocol

Study burden and risks

no burden, no risks. Possible additional X-ray radiation is neglectible.

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

ankle trauma

Exclusion criteria

bilateral complaints, former ankle fracture, age under 18 yrs

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Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	02-03-2016
Enrollment:	136
Туре:	Actual

Medical products/devices used

Generic name:	ultrasound application
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	04-12-2015
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

ССМО

ID NL54181.028.15