Gravity stress test in Weber B ankle fractures: an added value?

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What is the sensitivity and specificity of the gravity stress test compared with MRI?Is it possible to differentiate between stable and instable fractures with the gravity stress test?Is it possible to differentiate between partial and total rupture...

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

Summary

ID

NL-OMON40151

Source
ToetsingOnline

Brief title
WAXE

Condition

- Fractures

Synonym
ankle fracture, fibula fracture

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: Wetenschapsfonds MC Haaglanden

Intervention

Keyword: Gravity stress test, Weber-B fracture

Outcome measures

Primary outcome

The primary outcome will be the value of the gravity stress test compared to the MRI to distinguish between stable and instable fractures.

Secondary outcome

The secondary outcomes are the inter- and intra-observer variance of the gravity stress test, to dertermine the possibility to distinguish between partial and total rupture of the deltoid ligament and to assess the value to add the gravity stress test to the current diagnostics for ankle fractures.

Study description

Background summary

Ankle fractures are regulary seen at the emergency department. They represent about 10% of all fractures and according to expectations this number will increases over the years. The fracture can occure in the fibula (lateral malleolus) and/or the tibia (medial and/or posterior malleolus). Next to this there can be damage to de ligaments. The damage to the bones/ligaments distinguishes between a stable or an instable fracture. Instable fractures are generaly treated by operative fixation, stable fractures are generaly treated conservative.

Ankle fractures can be classified in different ways. The most commonly used classification is the Weber classification. We differentiate between Weber A, B and C fractures. Weber A fractures are distal of the syndesmosis, Weber-B fractures at the level of the syndesmosis and Weber C fractures are above the syndesmosis. Weber A fractures are stable and generaly treated as ligament damage. Weber C fractures are generaly instable and treated bij operative fixation. In Weber B fractures it is relevant to know if there is next to the fibula fracture damage to the bones and/or ligaments at the medial site of the ankle (deltoid ligament). The deltoid ligament is build up out of a deep and a

superficial part. The deep deltoid ligament is the primary stabilizer of the ankle and prevents lateral talar shift and external rotation of the talus. In patients with a Weber B fracture it is important to differentiate between a fracture with or without damage of the deltoid ligament for the consideration of conservative or surgical treatment.

To determine the integrity of the deep deltoid ligament we make use of an x-anterior posterior, x-lateral and x-Mortise view of the ankle. The amount of medial clear space widening has been somewhat variable in the literature but more than 5 mm is generally regarded as most reliable to predict rupture of the deltoid ligament. Adequate treatment for these patients is surgical treatment instead of conservative treatment. However in some cases it stays unclear if the deltoid ligament is ruptured or not.

Other diagnostic methods for determine the integrity of the deltoid ligament is the external rotation stress test and the gravity stress test. The external rotation stress test turn out to be a more painful, no correlation was found between a positive ankle stress test and the outcomes of the MRI and patients with a positive ankle stress test without clinical symptomes of deltoid ligament damage who were treated conservative kept all a good function of the ankle.

Not much research has been done to test the sensitivity and specifity of the gravity stress testt and there is no literature which compares positive ankle stress test with MRI results.

Study objective

What is the sensitivity and specificity of the gravity stress test compared with MRI?
Is it possible to differentiate between stable and instable fractures with the gravity stress test?
Is it possible to differentiate between partial and total rupture of the deltoid ligament with the gravity stress test?

Study design

All patients presenting at the emergency department of the MC Haaglanden with an acute Weber-B fracture are diagnosed and treated as said in the guidelines. Patients who meet the inclusion criteria will be informed about the trial in the emergency department and they will get an information package. In case the patient decides to participate in the trial, within one week an MRI and an gravity stress test wil be made. the conclusion of the MRI will be taken into account in the treatment plan of the fracture. All patients will be seen in follow-up at the regular times.

After all patients are included the gravity ankle stress test and de X-mortise will be coded anonymous and presented to a panel of 4 doctors. Two trauma surgeons and two radiologists will individual assess the X-mortise and the gravity stress test. They will assess the dislocation of the fracture, medial widening, the aspect of the syndesmose and indication to operate yes or no.

These results will be compared to the conclusion of the MRI, which will be assessed by an independent radiology assistent and an independent radiologist. The outcomes will be collected and analyzed by an independent researcher.

Analysis will show if the gravity ankle stress test has any value to distinguish between stable and instable fractures.

Next to this inter-observer study an intra-observer study will take place. All X-ray will be assess a second time by the same panel to determine the intra-observer variability

Study burden and risks

The patients have to visit the hospital one time extra in the first week after trauma to go into the MRI-scan. The treatment will not differ from the regular treatment, but in the future hopefully less patients need to be operated.

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

Patients with a Weber-B ankle fracture, above 18 years

Exclusion criteria

Patients with a contraindication for a MRI scan

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-05-2014
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	14-04-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL45705.098.13