

Tuning fork testing on ankle injuries

Submission date 21/05/2010	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 21/05/2010	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 21/07/2016	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

7442

Study information

Scientific Title

The tuning fork test: an accurate and efficient method of improving the diagnostic accuracy of the Ottawa ankle rules

Study objectives

A mixed method multicentre research study is used to establish the main aim of the study, which is to assess whether the specificity and therefore the diagnostic accuracy of the Ottawa Ankle Rules (OARs) can be improved by using them in conjunction with the Tuning Fork Test (TFT) on patients with twisting ankle injuries.

The study also aims to explore whether the use of the Tuning fork Test is acceptable to patients and staff, and if the results are favourable to compare the actual time spent in the Emergency care setting waiting for x-ray with time a patient could have been discharged if the tuning fork test is negative.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Southampton and SW Hampshire REC (A) approved on the 12th May 2009 (ref: 09/H0502/57)

Primary study design

Interventional

Study design

Multicentre randomised interventional diagnosis trial

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions

The tuning fork test consists of activating a 128Hz Gardner Brown tuning fork by holding the tuning fork by the stem and tapping the weighted tines on the fleshy side of the palm. The vibrating tuning fork is then placed at right angles to the body on both ankles. On the injured ankle this will be at the site of maximum tenderness and then 6 cm proximal (above). On the uninjured ankle the tuning fork will be placed at the corresponding sites on the injured ankle.

The study is a mixed methods study incorporating a quantitative diagnostic test study (the tuning fork test) with qualitative focus groups. The diagnostic test study is carried out once participants have been identified as having bony tenderness to either malleoli of their ankle or the distal fibula shaft. Once consent has been obtained the tuning fork test is carried out, randomised as to which ankle is tested first. In this study the un-injured ankle is used as a control group. the tuning fork test takes approximately 2 - 3 minutes maximum to complete. The participants then receive the standard ankle x-rays as per current practice. At this visit the participants are asked if the study team can contact them to take part in a focus group within 3 months of their visit. Participants are then contacted by letter and offered a choice of attending a focus group, withdrawing their consent to being contacted or giving permission to be contacted after the three month deadline regarding future focus groups. The focus groups last approximately one hour.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

The diagnostic accuracy of the Ottawa ankle rules is increased when used in conjunction with the tuning fork test. The tuning fork test and ankle x-rays are interpreted blind and then compared. The number of true and false negatives and positives is compared and will be displayed and analysed in a 2 x 2 table. When collecting the data the research nurse is aware of the results of both tests but the results will not be analysed until the sample size is met (n = 1300).

Key secondary outcome(s)

1. Demographics of the patient (i.e., gender, age, ethnicity)
2. Operator experience

Completion date

31/12/2010

Eligibility**Key inclusion criteria**

1. Ability to walk before the injury
2. Minimum age 12 years - no upper age limit, either sex
3. Injury to ankle by simple twisting mechanism - inversion/eversion
4. Identified as Ottawa positive - that is bony tenderness to lateral and/or medial malleolus

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Inability to give own informed consent
2. Patients who have a history of peripheral neuropathy from any cause
3. Patients who are pregnant will only be included if the risk of x-ray is considered to be less than the risk to the foetus from exposure to x-ray
4. Patients who are unable to walk prior to the incident will not be included as the OARs are designed to be used in patients who can walk before the incident

Date of first enrolment

01/06/2009

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Emergency Department

Portsmouth

United Kingdom

PO3 6LY

Sponsor information

Organisation

Portsmouth Hospitals NHS Trust (UK)

ROR

<https://ror.org/009fk3b63>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[HRA research summary](#)

[Study website](#)

Study website

11/11/2025

28/06/2023

11/11/2025

No

No

No

Yes