ISRCTN18630663 https://doi.org/10.1186/ISRCTN18630663

Tuning fork testing on ankle injuries

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.tuningfork.org.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Multicentre randomised interventional diagnosis trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 identifed 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 measure
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 a ware of the results of both tests but the results will not be analysed until the sample size is met (n = 1300).

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

Overall study start date
01/06/2009

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

Age group
Other

Sex
Both

Target number of participants
Planned sample size: 1300

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
England

United Kingdom

Study participating centre
Emergency Department
Portsmouth
United Kingdom
PO3 6LY

Sponsor information

Organisation
Portsmouth Hospitals NHS Trust (UK)

Sponsor details
Southwick Hill Road
Cosham
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England
United Kingdom
PO6 3LY

Sponsor type
Hospital/treatment centre

Website
http://www.porthosp.nhs.uk/

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Government

Funder Name
National Insititute for Health Research (NIHR) (UK) - Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
HRA research summary			28/06/2023	No	No