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Developing a prognostic tool for sprained ankles - the SPRAINED study

Submission date	Recruitment status
29/04/2015	No longer recruiting
Registration date	**Overall study status**
30/04/2015	Completed
Last Edited	**Condition category**
06/11/2019	Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Ankle sprains are one of the most common soft tissue injuries, mostly involving the ligaments (strong bands of tissue connecting together bones) on the outside of the ankle. Many people go to A&E with a sprained ankle every year, with the extent of injury varying from minor stretching to complete tear of the ligaments. The injury itself is painful and, unless minor, makes walking difficult. Symptoms generally last for weeks but, for a significant minority of people, they can actually last for months or years. Treatment generally depends on how bad the injury is but includes advice, self care, physiotherapy, ankle support, immobilisation and surgical repair. It is often very difficult to determine how serious the injury is at initial presentation, due to the swelling and pain caused by the injury. Simple tests like standing on one leg can help to determine how bad the injury is. Summaries of the research literature conclude there is a lack of good-quality evidence to help clinical decision-making. Probably as a result of this, there is no standard guideline for UK emergency department (ED) clinicians to follow, so clinical practice varies. Our group have completed a large study looking at which types of ankle support are best for severe sprains. We are planning to use the data from this trial to develop a tool that will help clinicians assess the risk of patients having a good or poor recovery. We will then check how well it works in a new set of patients recruited from A&Es around the UK.

Who can participate?
Adult patients with ankle sprains.

What does the study involve?
The participants taking part in this study are followed up at set times by questionnaire over nine months. We believe poor recovery means serious problems with level of activity, pain, confidence /stability of the ankle and/or recurrent injury. It is a combination of these measures that we try and predict using a combination of clinical and patient reported measures taken at A&E visits. Examples include age, sex, ability to walk, stability of the ankle and swelling. To aid us in developing the prognostic model, we review the current research literature and consult clinical experts and patients on what are important factors and outcomes. Decisions are made from a choice of candidate tools, options on the presentation of tools and potential additional measurements. The decisions will be made at a face to face meeting called a Modified Nominal Group which aims to gain consensus on decisions. At the end of the two and a half years of

research we aim to have developed a tool that will give a guide as to the chances of recovery for individual patients. A&E clinicians could then modify treatment or refer patients early for specialist treatment if they are at risk of poor recovery which could lead to more successful treatments and reduced costs to the NHS and society.

What are the possible benefits and risks of participating?
As this research is focused on using information, some of which is already routinely collected, the risk of harm is very low. The study will not interfere with ankle sprain treatment or any later rehabilitation participants might receive from their General Practitioner or Physiotherapist. We do not promise the study will help participants in particular, but the information we get from this study may help improve the NHS treatment for people with ankle sprains in the future

Where is the study run from?
A&E departments run by one of eight NHS trusts in the UK.

When is the study starting and how long is it expected to run for?
June 2015 to April 2017

Who is funding the study?
National Institute for Health Research (HTA programme).

Who is the main contact?
1. Mr Daryl Hagan (public)
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2. Dr David Keene (scientific)

Study website
http://www.nets.nihr.ac.uk/projects/hta/131906

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Synthesising a clinical Prognostic Rule for Ankle Injuries in the Emergency Department

Acronym
SPRAINED

Study objectives
To validate a clinical prognostic tool that helps to detect risk of poor outcome following ankle sprain for patients presenting to Emergency Departments/Minor Injury Units.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London-Chelsea, 10/04/2015, ref: 15/LO/0538

Study design
A multicentre cohort study for prognostic model validation

Primary study design

Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Ankle sprain

Interventions
In this validation study, we will recruit 675 adult patients with ankle sprains and follow these patients up by questionnaire at set time points over 9 months. We believe poor recovery means serious problems with level of activity, pain, confidence/stability of the ankle and/or recurrent injury. It is a combination of these measures that we will try and predict using a combination of clinical and patient reported measures taken at A&E visits examples are age, sex, ability to walk, stability of the ankle and swelling.

Intervention Type
Not Specified

Primary outcome measure
A composite measure indicating poor outcome for participants at 9 months, defined as either moderate/severe pain and/or moderate/severe functional difficulty and/or significant lack of confidence in the ankle and/or recurrent sprain.

Secondary outcome measures
1. Foot and Ankle Outcome Score (FAOS)
2. EuroQuol EQ-5D-3L
3. Health service resource use items

Overall study start date
01/11/2014

Completion date
30/04/2017

Eligibility

Key inclusion criteria

1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 16 years or above
3. Diagnosed with acute ankle sprain (<7 days old)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
675

Key exclusion criteria
1. Ankle fracture (excluding flake fracture <2mm)
2. Other recent (<3 months) lower limb fracture

Date of first enrolment
01/06/2015

Date of final enrolment
29/02/2016

Locations

Countries of recruitment
United Kingdom

Study participating centre
Oxford University Hospitals NHS Trust
Oxford
United Kingdom
-

Study participating centre
Heart of England NHS Foundation Trust
Birmingham
United Kingdom
-

Study participating centre

Sheffield Teaching Hospitals NHS Foundation Trust
Sheffield
United Kingdom
-

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Gloucester
United Kingdom
-

Study participating centre
University Hospitals Leicester NHS Trust
Leicester
United Kingdom
-

Study participating centre
North Bristol NHS Trust
Bristol
United Kingdom
-

Study participating centre
Royal Berkshire NHS Foundation Trust
Reading
United Kingdom
-

Study participating centre
Milton Keynes University Hospital NHS Foundation Trust
Milton Keynes
United Kingdom
-

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences
Nuffield Orthopaedic Centre
Windmill Road
Oxford
England
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OX3 7HE

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Following analysis of the internal and external validation of the tool, we will publish the findings in a peer-reviewed journal and disseminate through international conferences. We will also publish an HTA monograph of the project. Should we develop a suitable tool, we will make the

tool freely available on the web, with a simple registration to track areas and level of impact. We will investigate the possibility of using a mobile app for scoring the tool and utilising existing infrastructure used by clinicians to access decision tools e.g. MDCalc.com.

Intention to publish date
01/11/2017

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?
Results article	results	01/11/2018		Yes	No
Results article	results	05/11/2018	06/11/2019	Yes	No
HRA research summary			28/06/2023	No	No