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Clinical and cost effectiveness of different emergency department healthcare professionals in soft tissue management

Submission date	Recruitment status
20/08/2007	No longer recruiting
Registration date	**Overall study status**
07/10/2010	Completed
Last Edited	**Condition category**
01/11/2013	Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Clinical and cost effectiveness of different emergency department healthcare professionals in soft tissue management: a randomised trial

Acronym
MISTi Trial - Management In Soft Tissue injury Trial

Study objectives
This research is a trial of equivalence and investigates two null hypotheses:
1. The clinical outcome of adult patients presenting to the Emergency Department (ED) with a soft tissue injury (STI) is different between healthcare professionals
2. A doctor, Emergency Nurse Practitioner (ENP) and Extended Scope Physiotherapist (ESP) are not equally cost-effective in treating ED patients with soft tissue injuries

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by:
1. The Salisbury and South Wiltshire Ethics Committee, obtained on the 4th May 2006 (ref: 06 /Q2008/10)
2. The Faculty of Health and Social Care Ethics Committee at the University of the West of England, obtained on the 10th July 2006 (ref: HSC/06/07/57)

Study design
Pragmatic multicentre three-arm blinded randomised controlled trial of equivalence

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute peripheral musculoskeletal soft tissue injury

Interventions
Active control: Doctors (of all grades)
Intervention under investigation: Extended Scope Physiotherapist (ESP) and Emergency Nurse Practitioners (ENP). The intervention is the care provided by ESPs and ENPs compared to routine treatment by Doctors.

The patients are being followed up at 14 days and 8 weeks post treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

The primary aspect of the study will evaluate the clinical outcome of STIs following attendance at an emergency department, and the impact on quality of life. This will be done at baseline, and at 2 and 8 weeks using telephone interviews. The trial is powered to detect differences at the 8-week follow up.

Two validated and reliable functional outcome measures will be use in the trial: the Lower Extremity Functional Scale (LEFS) and the Quick Disabilities of the Arm, Shoulder and Hand (Quick DASH) questionnaire. Quality of life will be measured using the Short Form-12 Health Survey Questionnaire, Version 2 (SF-12v2).

Key secondary outcome(s))
The secondary aspect of the study will be an economic analysis identifying, quantifying and comparing the costs of both the emergency department visit and subsequent costs to the individual, NHS and society. Process measures associated with the three different types of healthcare practitioner (e.g. number of patients treated per hour and referral rate) will also be considered.

Completion date
01/10/2008

Eligibility

Key inclusion criteria
1. Adults (17 years or older), male or female
2. Patients presenting to an ED with a peripheral soft tissue injury with no immediately apparent fracture and is eligible for management by any of the three professional groups
2. Patients who consent to the study
3. All three practitioners working concurrently when the patient is admitted to the emergency department, to enable randomisation
5. A traumatic injury
6. Soft tissue injury less than 72 hours old
7. Patients will be included if they have minor grazes or wounds that require no treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
17 years

Sex
All

Key exclusion criteria

1. Systemic disease
2. Recent surgery
3. Previous ongoing injury to extremity
4. Intoxicated patients
5. Patients unable to give informed consent (e.g. dementia)
6. Open wounds/wounds (patient will be included if minor and insignificant)
7. Major deformities
8. Patients requiring opiate analgesia
9. Systemic disease (e.g. rheumatoid arthritis)
10. Healing fracture (less than 3 months)
11. Recent soft tissue injury
12. Head injuries (patient will be included if minor and insignificant)
13. Chest/rib injuries (patient will be included if minor and insignificant)
14. Neurovascular deficits
15. Less than 17 years of age
16. Obvious associated fractures
17. Patients who attend the ED when there is no ESP, ENP, doctor service running concurrently
18. Prisoners

Date of first enrolment
01/10/2006

Date of final enrolment
01/10/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Academic Department of Emergency Care,
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
University of the West of England (UK)

ROR
https://ror.org/02nwg5t34

Funder(s)

Funder type
University/education

Funder Name
University of the West of England (UK) - funded as part of a PhD bursary

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?
Results article	results of pilot study	01/05/2006		Yes	No
Results article	results	08/11/2012		Yes	No
Results article	results	03/01/2013		Yes	No