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Can ambulance paramedics use FRAX (the WHO Fracture Risk Assessment Tool) to help GPs improve future fracture risk in patients that fall?

Submission date
13/03/2014

Recruitment status
No longer recruiting

Registration date
13/03/2014

Overall study status
Completed

Last Edited
12/10/2018

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] 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

Contact name
Dr Shane Clarke

Contact details
Rheumatology Unit
The Courtyard
Old Building, Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW
-
s.clarke@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14057

Study information

Scientific Title
Can ambulance paramedics use FRAX (the WHO Fracture Risk Assessment Tool) to help GPs improve future fracture risk in patients that fall?

Study objectives
Broken bones are painful, often disabling, and cost the NHS £2 billion annually. Tablets reduce the risk of having a fracture in the most vulnerable but the number of people at high risk taking the right treatment (about 1 in 3) is unacceptably low.

Part of the problem is poor communication between healthcare providers; for example, GPs are seldom told about their patients who fall by the attending ambulance service. Falls and fracture are closely linked. Each fall that results in an ambulance call might represent an important opportunity to assess a patients fracture risk using a computer programme called FRAX®.

The proposed project is a feasibility study to help us design a full trial. The full trial will find out if ambulance crew can collect information from people that fall and help GPs target treatment for osteoporosis at those patients most likely to have a future fracture.

In this feasibility study we want to find out whether ambulance staff can obtain the necessary information to estimate a patients fracture risk, and if the GPs will act on the information given to them. We also require information to help us work out how many patients we will need to recruit, and might be at a high risk of fracture. It is also essential to ensure the study methods are acceptable to patients, ambulance staff and GPs before we plan the main trial.

Our study involves ambulance staff asking patients additional questions after they have fallen over, and the design includes a control group, whose members will not be informed of their fracture risk. These ethical issues were considered by members of the public.

The proposal was felt to be acceptable, with real potential to improve osteoporosis care. A large Medical Research Council study has already successfully used a similar approach.

More details can be found at: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=14057

On 04/06/2014 the anticipated end date was changed from 28/03/2014 to 01/07/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
12/SC/0604

Study design
Randomised; Interventional; Design type: Screening, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England, Injuries and Emergencies; Subtopic: Not Assigned, Injuries and Emergencies (all Subtopics); Disease: Injuries and Emergencies, All Diseases

Interventions
Calculate future fracture risk: Paramedics will calculate future fracture risk in patients that fall; Transmit fracture risk GP, Paramedics will transmit calculated future fracture risk to patients GPs; Follow Up Length: 3 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Patients on treatment; Timepoint(s): Proportion of patients taking new treatment to reduce future fracture risk

Secondary outcome measures
Appropriate investigations; Timepoint(s): The proportion of patients in control and intervention group that are referred for DXA or blood test

Overall study start date
28/06/2013

Completion date
01/07/2014

Eligibility

Key inclusion criteria
Men and women aged over 50 who fall (inside or outside their place of residence), call an ambulance, and are attended by study paramedics

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100; Description: 50 control 50 intervention

Key exclusion criteria
1. Patients who, in the paramedics opinion, are medically unstable and for whom it would not be appropriate to delay treatment to ask study questions (for example where the paramedics suspect a cardiac incident).
2. Patients who have fallen in a public place and n the opinion of the treating paramedics should be conveyed without delay.
3. Patients who are deemed to lack capacity (according to the Mental Health Act [2005]) but for whom there is no available carer or consultee.
4. Patients who are admitted to hospital for 24 hours or more. These patients will need to be excluded by the RF prior to consent (pre-existing service arrangements cover inpatients and our principal target population is in primary care).

We will continue to monitor patients who fall twice or more during the study period, but count the first fall as the index event. Only the first eligible fall will trigger entry to the study.

Date of first enrolment
28/06/2013

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Rheumatology Unit
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust (UK)

Sponsor details
Research & Development
Upper Maudlin Street
Bristol
England
United Kingdom
BS2 8AE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0711-25070

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?
Protocol article	protocol	03/09/2014		Yes	No
Results article	results	20/04/2015		Yes	No