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Southampton arm fracture study

Submission date
07/05/2019

Recruitment status
No longer recruiting

Registration date
13/05/2019

Overall study status
Completed

Last Edited
04/05/2022

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
A third of people aged over 65 years fall every year, leading to fractures in 10-15%. Arm fractures are often the first sign of fragile bones
(osteoporosis). 25% of these patients will suffer another fracture, often of the hip, within 10 years. National guidelines recommend routine
assessment of people with arm fractures for fragile bones to help prevent subsequent hip fractures.
The risk of falling is increased in people who are frail or have lost muscle strength with ageing (sarcopenia). Both of these conditions are more common in patients who suffer from fragile bones. Identifying and managing frailty or sarcopenia when we age could reduce future falls and fractures.

Who can participate?
We will study 100 people aged 65 or over with an arm fracture from three fracture clinics in Southampton, UK.

What does the study involve?
If a patient agrees to take part, the research team will meet him/her in the fracture clinic. After explaining the study and obtaining written consent from participants, we will ask them some questions about their general health and wellbeing. We will also measure their weight and walking speed across the room. We will measure grip strength by asking them to squeeze a special instrument. Finally, we will test the percentage of water and muscle in their body with a small electrical pulse. We will telephone participants twice, in 3 months and 6 months' time, to ask if they have had any falls or fractures since this visit to the fracture clinic. And we will also ask them about your daily activities and wellbeing.

What are the possible benefits and risks of participating?
There are no risks or disadvantages associated with taking part in the study. The research assessments are expected to take about 30-40 minutes. The potential benefits of this research include referring high-risk patients for a more detailed assessment at a local clinic run by a consultant in Medicine for Older People. We will learn more about the best way to predict falls and fractures in older people. We will also learn whether we can do these assessments in a busy fracture clinic.

Where is the study run from?
Southampton General Hospital, UK

When is the study starting and how long is it expected to run for?
March 2019 to March 2020

Who is funding the study?
Research for Patient Benefit Programme, NIHR, UK

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MED1580; 40695

Study information

Scientific Title
Assessment of patients aged 65+ years with an upper limb fracture for frailty and sarcopenia for the prevention of future falls and fractures: a feasibility study

Study objectives
We hypothesise that assessing people with upper limb fractures for sarcopenia and frailty, in addition to osteoporotic fracture risk, can offer an opportunity to detect these conditions and use appropriate existing care pathways that address these conditions to reduce the number of falls and fractures in future.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/12/2018, North East-Newcastle and North Tyneside 1 NRES Committee (NHSBT Newcastle Blood Donor Centre, Holland Dr, Newcastle upon Tyne, NE2 4NQ; 0207 104 8089; nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net), ref: 18/NE/0377.

Study design
Mixed methods feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Screening

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
Frailty and sarcopenia among older people with upper limb fractures

Interventions
Patients attending fracture clinic will be assessed for frailty and sarcopenia in addition to the usual care (which involves fracture review, determining patients' risk of future fracture and consideration of screening and/or treating for osteoporosis).
Patients identified as having either frailty or sarcopenia will be referred to existing local geriatric medical services for specialist review including comprehensive geriatric assessment (CGA). This is a multidisciplinary assessment and management of patients using health and social care pathways. These may include medical review of comorbidities and optimisation of medication; consideration of unmet needs in physical, cognitive, and social domains; and referrals to other clinical, social care or voluntary services. These actions and referrals will be varied and focussed on the individual patient's recognised needs and their wishes.

Eligible patients will be assessed by a senior researcher for frailty (using 6 validated measures: Fried frailty phenotype, FRAIL scale, PRISMA, e-FI, SOF, and CFS) and sarcopenia using two tools (SARC-F and EWGOPS). Those who identified to have frailty or sarcopenia will be referred for further assessments.

Intervention Type
Mixed

Primary outcome measure
1. Feasibility of assessing frailty and sarcopenia among patients with upper limb fracture: This will be determined by:
a) the percentage of people that are assessed by each tool (adequacy)
b) availability of required data and the number of missing data
c) equipment (including cost, availability of functioning equipment and frequency of calibration)
d) the time for carrying out each assessment
e) acceptability of the tools by staff and patients (via interviews).
This will determine the prevalence of frailty and sarcopenia among the study participants and which measures of assessing frailty and sarcopenia are most feasible in this population
2. Feasibility of using existing care pathways: Patients identified as having either frailty or sarcopenia will be referred to local geriatric clinical services for specialist review as outlined in the intervention. The actions instigated from these assessments and referrals will be varied and individualised according to patient's needs and wishes. These referrals may lead to additional attendance at out-patients, primary care or exercise classes for example. We will report the number of patients identified to have frailty and/or sarcopenia who are referred to CGA, the number of those who receive CGA, and the number and type of follow up interventions.

Secondary outcome measures
1. Falls and fractures: participants will be asked to fill in a falls diary recording the date, suspected cause, location and the consequences of each fall. They will be contacted by telephone at 3 and 6 months after recruitment to collect self-assessed information on falls and fractures within the previous 3 months. This will establish whether quarterly data collection is suitable for the future trial.
2. Mortality: death rates within 6 months of recruitment will be collected from the hospital patient administration system (PAS)
3. Future outcome measures: Baseline data on nutritional, physical and cognitive factors which may be associated with frailty and sarcopenia status will be collected. Quality of life and physical function will be measured at baseline, and 3 months and 6 months after recruitment. The feasibility of using each of these assessments in this patient group will inform which instrument will be used in the future trial.
4. Costs and healthcare resource use: We will capture the number, type and resource implications of these referrals during the 6 months post recruitment via quarterly phone calls with participants. We will also abstract data on healthcare resource use from the hospital patient administration system (PAS) and primary care electronic records.

Overall study start date
01/01/2019

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. Aged 65 + years
2. Single arm fracture (wrist or upper arm)
3. Referred directly from A&E, GP, local minor injuries unit or other fracture clinics
4. Able to give informed consent and not previously diagnosed with frailty and/or sarcopenia

Participant type(s)
Mixed

Age group
Senior

Sex
Both

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
1. Pathological fractures
2. Multiple or lower limb fractures
3. Active cancer diagnosis
4. Care home residents

Date of first enrolment
01/03/2019

Date of final enrolment
01/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Southampton Foundation NHS Trust
Southampton General Hospital
Tremona Road

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SO16 6YD

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

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Sponsor type
University/education

Website
https://www.southampton.ac.uk/medicine/about/staff/ki1r14.page

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme (PB-PG-0317-20043)

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Findings from the study will be published in peer-reviewed journals and/or specialist open access journals. Research findings will be presented locally, nationally, and internationally. We will work with our PPI team to further develop and implement the dissemination and engagement strategy including the development of reports and approaches to engage the community. We will disseminate the findings via social media (facebook and twitter), local groups and 3rd sector e.g. Age UK and National Osteoporosis Society.

Intention to publish date
30/03/2022

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/08/2019	01/04/2021	Yes	No
Results article		06/01/2022	04/05/2022	Yes	No
HRA research summary			28/06/2023	No	No