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The Nottingham spinal health study

Submission date
29/11/2016

Recruitment status
No longer recruiting

Registration date
20/12/2016

Overall study status
Completed

Last Edited
13/03/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Fragility fractures are a type of fracture which occurs as a result of normal activity, such as a fall from standing height or less. Low-trauma vertebral fractures are fragility fractures affecting the small bones that make up the spine (vertebra). It is most commonly caused by osteoporosis, a long-term condition where bones become brittle and break easily. Vertebral fragility fractures can lead to pain, limitation in daily activities, and is associated with further fragility fractures and worse healthcare outcomes. The majority of vertebral fragility fractures are treated in the community, and so those that do need admission to hospital are more likely to have sustained a serious fracture and be in significant pain and disability. This specific group of patients has not been robustly studied and this study aims to describe the characteristics of patients admitted to hospital with a vertebral fragility fracture, their care in hospital and health outcomes associated with it at six months.

Who can participate?
Adults aged 50 years and over who have been admitted to hospital because of a vertebral fragility fracture or suspected vertebral fragility fracture.

What does the study involve?
Participants who have been admitted to hospital because of a vertebral fragility fracture or suspected vertebral fragility fracture are approached by the study team to complete a number of questionnaires. In addition, their medical records are reviewed for background information about their health. Six months later, participants are contacted and repeat the initial questionnaires to look at the long-term outcomes of their fracture.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to those taking part.

Where is the study run from?
Queens Medical Centre, Nottingham (UK)

When is the study starting and how long is it expected to run for?
August 2016 to March 2018

Who is funding the study?
Dunhill Medical Trust (UK)

Who is the main contact?
Dr Terence Ong
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16HC004

Study information

Scientific Title
Nottingham Spinal Health (NoSH) Study: A cohort study of vertebral fragility fractures admitted to hospital

Acronym
NoSH

Study objectives

The aim of this study is to describe characteristics of adult patients admitted to hospital with vertebral fragility fractures and their associated outcomes. Findings from this study will inform the potential development of a specialist service for vertebral fracture management in hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval provided by the East of England - Cambridge Central Research Ethics Committee, 22/07/2016, ref: 16/EE/0249

Study design
Single centre prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Vertebral fractures, including those in patients with osteoporosis

Interventions
Patients with a diagnosed or suspected diagnosis of an acute vertebral fragility fracture will be invited to participate in the study. Data collection will be conducted on admission, at discharge from hospital and at 6 months follow up post-discharge. Range of data collected are detailed in the accompanying section of this application. Data will be gathered from patient questionnaire and their medical case notes. This observational study will not interfere with the care delivered as part of their hospital admission.

Intervention Type
Other

Primary outcome measure
1. Pain is measured using an 11 point numeric rating scale at baseline (on admission to hospital), on discharge from hospital and at 6 months
2. Mood is measured using the Geriatric Depression Scale at baseline (on admission to hospital) and at 6 months
3. Cognition is measured using the Montreal Cognitive Assessment at baseline (on admission to hospital) and at 6 months
4. Disability is measured using the Elderly Mobility Scale, Barthel Index, Nottingham Extended

Activities of Daily Living and Roland Morris Disability Questionnaire at baseline (on admission to hospital) and at 6 months

Secondary outcome measures
1. Hospital inpatient mortality and overall mortality are measured by analysing healthcare records at 6 months
2. Hospital related outcomes measured by analysing hospital paper and electronic healthcare records on patients discharge - length of stay, discharge destination/changes in residency, hospital related complication (hospital acquired infection, pressure sore, venous thromboembolic event, delirium and neurological impairment)
3. Quality of life post-hospitalisation for vertebral fractures is measured using the EQ-5D measured at 6 months
4. Healthcare resource utilisation after hospital discharge is measured through self or proxy reporting at 6 months

Overall study start date
10/08/2016

Completion date
15/03/2018

Eligibility

Key inclusion criteria
1. Adults aged 50 years and over
2. Admitted to hospital with either a low trauma or atraumatic vertebral fragility fracture or suspected vertebral fragility fracture pending radiology investigation. A low trauma fracture is a fracture sustained after a fall from a standing height or less. A diagnosis of vertebral fracture is made radiologically (i.e. x-ray imaging, computerised tomography (CT), magnetic resonance imaging (MRI) of the spine) or bone (scintigraphy) scan.
3. While in hospital was diagnosed with a vertebral fragility fracture unrelated to their index admission

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Patients without a vertebral fracture
2. Patients admitted electively to hospital for management of their vertebral fracture
3. Patients transferred from another hospital
4. Vertebral fracture sustained as a result of a high impact injury, e.g. road traffic accident, fall

down a flight of stairs, etc.
5. Patients presenting with a concomitant fracture elsewhere
6. Patients admitted to hospital under a major trauma pathway
7. Patients with known or suspected malignancy
8. Patients with known primary bone disorder (e.g Paget's disease) other than osteoporosis
9. Patients terminally ill or moribund

Date of first enrolment
28/09/2016

Date of final enrolment
18/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queens Medical Centre
Nottingham University Hospitals NHS Trust
Derby Road
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

Sponsor details
Research and Innovation
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+44 1159 249924 ext 70659
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Sponsor type
Hospital/treatment centre

Website
http://nuhrise.org/

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Dunhill Medical Trust

Alternative Name(s)
The Dunhill Medical Trust, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned dissemination of findings through participation at relevant conferences, publication in peer-reviewed journals, clinical and research networks, and engagement with our patient and public involvement group.

Intention to publish date
16/03/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from terenceong@doctors.org.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V3	22/09/2016	12/01/2017	No	Yes
Basic results		14/03/2019	26/03/2019	No	No
HRA research summary			26/07/2023	No	No