

# The Nottingham spinal health study

<b>Submission date</b> 29/11/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/12/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/03/2020	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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  
terenceong@doctors.org.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Quality of life

### **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(s)**

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

### **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**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

**ROR**

<https://ror.org/05y3qh794>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Dunhill Medical Trust

**Alternative Name(s)**

The Dunhill Medical Trust, Dunhill Medical Trust, DunhillMedical, DMT

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## Results and Publications

## 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](mailto:terenceong@doctors.org.uk)

## IPD sharing plan summary

Available on request

## Study outputs

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