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A study to compare the clinical effectiveness and cost effectiveness of Medial Branch Nerve Block (MBNB) to routine Vertebroplasty (VP) surgical care in hospitalised older people with painful vertebral fracture

Submission date
21/05/2021

Recruitment status
No longer recruiting

Registration date
24/05/2021

Overall study status
Completed

Last Edited
10/06/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoporosis is a common chronic disease resulting in fragile bones. Across Europe, 22 million women and 5 million men have osteoporosis. Fractures of the spine, 'vertebral fragility fracture-VFF' are the most common osteoporotic fracture. These constitute a major health problem, leading to both acute and chronic back pain, substantial spinal deformity, functional disability, decreased quality of life and increased mortality. Many patients who sustain a VFF have mild to moderate symptoms, however a significant proportion develop substantial pain and disability which require hospital admission. Non surgical treatment for these patients consists of bed-rest, painkillers and, in some units spinal bracing, but these are poorly tolerated, with the adverse effects of painkillers and immobilisation leading to additional health problems. Surgical treatment-vertebroplasty (VP) is a minimally invasive, image-guided key-hole procedure that involves injection of bone cement into the fractured spine, to provide pain relief and stability. This is routinely undertaken for those patients with continuing pain, and has been found to be safe, effective and recommended by NICE. However, another potential treatment may be to offer a spinal nerve block. This is much less invasive and avoids the need of a general anaesthetic. We hypothesise that a spinal nerve block will be 'as effective' as VP in reducing acute pain and allowing early return to function. This would alter the management of these patients in hospital and given the cost of a spinal nerve block in only one tenth of VP, this may have significant financial savings to the NHS. Given the scale of this problem and the simplicity of the proposed intervention, we believe that if the results are successful, they will be rapidly adopted by the NHS in hospitals.

Who can participate?
Patients aged 70 years and over admitted to hospital who has been diagnosed with painful spinal fracture.

What does the study involve?
Patients presenting to the Nottingham University Hospital NHS Trust with an acute painful VFF and awaiting spinal surgery will be recruited into the study. Those who indicate that they are interested in hearing more about the trial will be introduced to the research team. The research team will explain the details of the study provide a patient information sheet (PIS) and answer any questions. Patients will have the opportunity to discuss this with their family and to ask any questions they might have. Whenever possible, they will have at least 24 hours to consider participation in the study before giving informed consent.
A member of the research team will make contact with the participant after they have been recruited into the study to see how they are doing. There will be:
1. A face-to-face meeting a week after joining the study
2. A telephone follow-up four weeks after joining the study
3. A telephone follow-up eight weeks after joining the study

What are the possible benefits and risks of participating?
The benefit of taking part of this study is patients will receive treatment for the fracture of their spine, which would either be via Vertebroplasty(VP), which is considered to be standard of care or via Medial Branch Nerve Block (MBNB), which is considered to be less invasive and postulated to be as effective as VP in reducing pain due to your fracture.
The risk involve is exposure to a small amount of ionising radiation, but patient would still be exposed to this even if they are not participating in the research.

Where is the study run from?
Nottingham University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2021 to December 2022

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Prof. Opinder Sahota, opinder.sahota@nuh.nhs.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
293210

Central Portfolio Management System (CPMS)
49269

Study information

Scientific Title
Spinal Medial Branch Nerve Root Block (MBNB) intervention compared to standard care-Vertebroplasty (VP) for the treatment of painful osteoporotic vertebral fractures in hospitalised older patients: a feasibility study. The AVERT (Acute VertEbRal AugmentaTion) Study

Acronym
AVERT

Study objectives
A spinal nerve block will be ‘as effective’ as VP in reducing acute pain and allowing early return to function

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/04/2021, Yorkshire & The Humber – Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8109; bradfordleeds.rec@hra.nhs.uk), ref: 21/YH/0065

Primary study design
Interventional

Study design
Randomised; Both; Design type: Treatment, Surgery, Qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of painful osteoporotic vertebral fractures

Interventions

Participants will be randomly allocated to receive standard care-vertebroplasty or spinal nerve block treatment.
Participants of the study will be identified by the by the ward clinical staff when they are admitted to hospital and diagnosed with an acute fracture of the spine. Should they be interested in discussing about the study will be introduced to the research team. The research team will then assess the eligibility of the patient by referring to the inclusion and exclusion criteria stated in the study protocol.

Once this criteria has been met, the research team will then approach the patient and explain their role and provide an information sheet and answer any questions. Patients will then have at least 24 hours to consider if they would like to be part in the study. They will be informed that entry to the study will be entirely voluntary, and that their treatment and care will not be affected by their decision. They will also be informed that, if they did agree to participate, they can withdraw at any time and this will not impact on future care. They may be asked to give reasons for withdrawal to help with the study, but will not be obliged to.

Participants will be allocated by chance, at random, which will be done via an electronic system, to receiving either standard care vertebroplasty or the spinal nerve root block treatment. Participants will be allocated on a 1:1 ratio, meaning that 15 participants will be allocated to having treatment with the nerve block and 15 participants will be allocated to vertebroplasty. Participants and their GPs will be notified of the allocated treatment.
The allocated procedure will be undertaken within 72 hours of randomization, as part of the routine spinal emergency surgical theatre.

Following treatment, we will follow up participants at 1 week, 4 weeks and 8 weeks. The follow ups will be conducted as a face to face interview in hospital at week 1, taking up to 30 minutes. At week 4 and 8, these will be shorter interviews over the telephone or face to face (if the participant is still in hospital).

In a small group of patients and a small number of clinicians, we will also undertake semi structured interviews. We aim to interview 10 patients and 5 clinicians. The purpose of this is to gain an insight into the design of the study and how they felt during the whole process and would seek recommendations for improving the study design.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Measured at weeks 1, 4, and 8 post randomisation and at the completion of data collection using data collected on Redcap Cloud:
1. Number of eligible patients
2. Rate of participant recruitment and randomisation
3. Reasons why participants are not recruited or randomised
4. Rate of participant adherence to randomisation (cross-over) and retention
5. Completion of study rates and reasons for non-completion
6. Completeness of data (see secondary outcome measures)
7. Time from randomisation to delivery of the intervention

Key secondary outcome(s)
Outcomes for subsequent definitive trial measured at 1, 4, and 8 weeks from the time of intervention:

1. Functional disability as measured by the 24 point Roland Morris Disability Questionnaire (RMDQ)
2. Pain as measured by the 0-11 NRS
3. Quality of Life as measured by the EQ5D-5L and (where appropriate) proxy EQ5D-5L
4. Activities of daily living as measured by the Nottingham Extended Activities of Daily Living (NEADL) scale
5. Record of pain medication use (using the opioid dose equivalence table)

Completion date
30/12/2022

Eligibility

Key inclusion criteria
1. Patients aged 70 years and over admitted to hospital
2. Ambulatory prior to injury
3. <3 weeks from date of injury
4. Numeric Rated Pain Scale (NRS) 7 or more on standing
5. MRI confirmed oedema at the site of fracture
6. Ability to adhere to study procedures and complete follow-up

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Chronic back pain requiring opiate use
2. Substantial fracture retropulsion; acute infection, spinal malignancy
3. 3 or more acute vertebral fractures
4. Bed bound prior to fracture
5. Receiving palliative care
6. Lack of capacity and no consultee
7. Spinal deformity which contraindicates VP

Date of first enrolment
01/06/2021

Date of final enrolment
30/08/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen's 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
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR201937

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing plan as of 14/08/2023:
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication. The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Opinder Sahota, opinder.sahota@nuh.nhs.uk.

Previous IPD sharing plan:
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication. The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/10/2023	10/06/2025	Yes	No
Protocol article		13/06/2022	15/06/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other unpublished results			14/08/2023	No	No
Participant information sheet	version v1.2	12/04/2021	24/05/2021	No	Yes
Participant information sheet	version v1.1	26/03/2021	24/05/2021	No	Yes
Protocol file	version V1.2	07/05/2021	24/05/2021	No	No