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Physiotherapy Rehabilitation for Osteoporotic Vertebral fracture (PROVe)

Submission date
11/05/2012

Recruitment status
No longer recruiting

Registration date
15/05/2012

Overall study status
Completed

Last Edited
29/08/2019

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:
25,000 people in the UK have vertebral (spine) fractures related to their osteoporosis each year and many of these are referred for physiotherapy to help them recover after their fracture(s). Physiotherapy includes a variety of treatment options, such as exercise programmes or hands on treatment like massage. At the moment there is some research evidence which suggests that physiotherapy may help to ease pain and help patients get back to their normal activities of daily life as soon as possible. However, we do not know which type of physiotherapy is most helpful to people, how much this treatment is costing the NHS, or what patients think of their treatment. The research question: Which type of physiotherapy helps patients with osteoporosis recover most after vertebral fracture? The study will test exercise and manual treatments and compare patients who have had these treatments to patients who have usual care with no physiotherapy treatment. The research will also provide information about treatment costs, safety and about what patients think about their treatment.

Who can participate?
Men and women with a diagnosis of primary osteoporosis confirmed by radiograph and with at least 1 painful vertebral fracture. Female participants will need to have passed menopause. All participants will have had appropriate fracture prevention therapy, be able to walk independently with or without an aid for at least 10 metres and be able to participate in a physiotherapy programme.

What does the study involve?
Participants will be asked to attend three assessments, the first before any treatment happens, the second 14 weeks later and the third twelve months after the study starts. After the first assessment a computer programme will decide which study group the person will join: treatment as usual, manual physiotherapy or exercise physiotherapy groups. Every participant will continue taking any osteoporosis medication, and will be offered education about osteoporosis and support through the trial with telephone calls every 2 months. In addition, the treatment groups will be offered 6 sessions of physiotherapy and asked to carry out some activities and exercises at home.

What are the possible benefits and risks of participating?
All participants will have access to usual care, and no treatment will be withheld from any participant. There is a slight risk that the treatments could increase pain or may lead to an increase in further fracture rates (25% fracture rates may be seen in the control group) and we will monitor these carefully. If the trial is successful, future patients will benefit from the clarification of the best treatment package for treating this condition. Alternatively, we may demonstrate that physiotherapy interventions are not effective for this condition, thus allowing National Health Service resources to be saved and redirected to other more effective treatments

Where is the study run from?
University of Oxford

When is study starting and how long is it expected to run for?
It is anticipated that recruitment will start early in 2013. Participants will be enrolled into the study for a period of 18 months; with follow up of patients for one year. In total the study will run for 4 years.

Who is funding the study?
NIHR Health Technology Assessment Programme

Who is the main contact?
Dr Karen Barker
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Contact information

Type(s)
Scientific

Contact name
Dr Karen Barker

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
N/A

Study information

Scientific Title
Physiotherapy Rehabilitation for Osteoporotic Vertebral fracture (PROVe)

Acronym
PROVe

Study objectives
Either manual therapy or exercise therapy will offer improved functional outcome than treatment as usual.

Sub study: Reliability of physical outcome measures for posture and back muscle strength. 60 patients completing 3 different measures to assess suitability, utility and reliability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central, 08/08/2012, ref: 12/SC/0411

Sub study: South Central, 07/08/2012, ref: SC 12/ 0390

Study design
Adaptive design multi-centred, three-arm randomised controlled trial with blinded assessments.

Sub study: Non-randomised observational cross-sectional study of three measures of spinal posture

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Osteoporosis

Interventions
Physiotherapy either manual therapy or exercise based therapy - up to 7 sessions

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
QUALEFFO 41 Quality of Life questionnaire

Sub study- Inclinometer, tragus to wall, flexicurve measures for relaibility

Secondary outcome measures
1. Timed load stand test
2. Spinal posture
3. Short performance physical battery
4. Functional reach test, 6 minute walk, PASE questionnaire, EQ5D, pain VAS

Overall study start date
01/01/2013

Completion date
31/03/2018

Eligibility

Key inclusion criteria
1. Men and women
2. A diagnosis of primary osteoporosis confirmed by radiograph or by DEXA scan of <= -2.5 at lowest lumbar level
3. At least 1 painful vertebral fracture sustained previously.
4. At different times post vertebral fracture and with different numbers and sites of fractures
5. Female participants will need to be postmenopausal as defined by the date of their last period which should be more than 2 years previously.
6. All participants will have had appropriate fracture prevention therapy under NICE TA 161, be able to walk independently with or without an aid at least 10 metres and be able to participate in a physiotherapy programme.

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
600

Total final enrolment
615

Key exclusion criteria
1. Have any condition which might make participating in physiotherapy unsafe, including severe unstable cardiovascular or pulmonary disease, osteoporosis secondary to metabolic bone disorders or other disease and neurological disorders.
2. Those whose primary problem is back pain with radiating pain into the lower limb will be excluded as will individuals who have had vertebroplasty, facet joint injection or physical therapy e.g. chiropractic, osteopathy or physiotherapy treatment for back pain in the previous 12 weeks

Date of first enrolment
01/01/2013

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospitals NHS Trust
Oxford
United Kingdom
OX3 7HE

Sponsor information

Organisation
Oxford University Hospitals NHS Trust (UK)

Sponsor details
c/o Ms Heather House
Medical Research Services
Churchill Hospital
Old Road

Oxford
England
United Kingdom
OX3 7LJ

Sponsor type
Hospital/treatment centre

Website
http://www.ouh.nhs.uk/

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK) ref: 10/99/01

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal.

Intention to publish date
31/03/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study 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	protocol	14/01/2014		Yes	No
Results article	results	01/08/2019	29/08/2019	Yes	No