

Physiotherapy Rehabilitation for Osteoporotic Vertebral fracture (PROVe)

Submission date 11/05/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 15/05/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/08/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

QUALEFFO 41 Quality of Life questionnaire

Sub study- Inclinator, tragus to wall, flexicurve measures for reliability

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Oxford University Hospitals NHS Trust

Oxford

United Kingdom

OX3 7HE

Sponsor information

Organisation

Oxford University Hospitals NHS Trust (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

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?
Results article	results	01/08/2019	29/08/2019	Yes	No
Protocol article	protocol	14/01/2014		Yes	No