

Northumbria osteoporosis project: Group clinics

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| Submission date 19/06/2017 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 01/09/2017 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 26/10/2017 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Osteoporosis (weak or brittle bones) is common and often missed. Group clinics can be an option to try and diagnose this condition. Group clinics are effective and efficient in patients with arthritis (a type of swelling in the joints); however it is unsure if group clinics work for osteoporosis. The aim of this study is to see if a group clinic led by a pharmacist were as effective as usual care for people with osteoporosis.

Who can participate?

Adults over 50 with high fracture risk.

What does the study involve?

Participants are randomly allocated using a random number table to either the intervention or the control group. Those in the intervention group attend a single Pharmacist-led group clinic. Those in the control group receive the usual care, which is a single consultation delivered by Pharmacist. Participants are followed up for 12 months for medication use.

What are the possible benefits and risks of participating?

There are no benefits with participating. There are no direct risks, however participants may not like being seen in a group setting.

Where is the study run from?

This study is being run by Northumbria Healthcare (UK) and takes place practices in Northumberland CCG (UK).

When is the study starting and how long is it expected to run for?

August 2010 to August 2018

Who is funding the study?

1. National Osteoporosis Society (UK)
2. National Institute for Health Research (UK)

Who is the main contact?

1. Dr Fraser Birrell (Scientific)
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2. Mrs Norma Cardill (Public)
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Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

12765

Study information

Scientific Title

Northumbria Osteoporosis Project: A randomised controlled trial of managing patients needing bone protection treatment through group clinics vs usual one to one care

Study objectives

There will be no significant difference between medicines adherence as measured by Mean Possession Ratio (MPR) when compared with usual care (1:1 clinic), in patients being prescribed bisphosphonates for fracture prevention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee North East - Newcastle & North Tyneside 1, 21/12/2010, 10/H0906/88

Study design

Randomised; Both; Design type: Not Specified, Not Specified, Qualitative

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

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

Specialty: Musculoskeletal disorders, Primary sub-specialty: Metabolic Bone Disease

Interventions

Participants with high risk of fracture were identified by their practice. They were sent a letter to invite them to take part in the study. Those accepting were randomised to group clinic or usual care and seen once. In either setting they had education about osteoporosis and prescribed standard treatment.

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Intervention Type

Behavioural

Primary outcome measure

Mean possession ratio (MPR) of bisphosphonates is measured using practice prescription records at 12 months

Secondary outcome measures

1. Persistence with treatment is the time (in months) before the drug is no longer requested measured using practice prescription records by month up to 12 months
2. Patient satisfaction with group clinics, enabling factors and active ingredients were explored with qualitative interviews of osteoporosis group clinic participants and comparison with an established, but co-designed and therefore evolving inflammatory arthritis group clinic model
3. Cost analysis of the intervention was restricted to staff costs of, as assumptions of other costs being equivalent were met

Overall study start date

24/08/2010

Completion date

31/08/2018

Eligibility**Key inclusion criteria**

1. Patients identified as high risk of an osteoporotic fracture, needing treatment
2. Patients aged 50 years and over
3. Patients giving informed consent to the study

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 214; UK Sample Size: 214

Key exclusion criteria

1. Patients not eligible for first line treatment as defined by North of Tyne Osteoporosis Guidance (encompassing FRAX calculation and NOGG guideline)
2. Patients not wishing to participate in the study
3. Patients unable to consent to participate in the study
4. Patient contraindications to bisphosphonates (upper gastrointestinal problems, severe impairment GFR<35ml/min, previous intolerance)
5. Terminally ill patients
6. Housebound patients

Date of first enrolment

01/06/2012

Date of final enrolment

31/07/2018

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Northumbria Healthcare NHS Foundation Trust

North Shields

United Kingdom

NE29 8NH

Study participating centre

Bedlingtonshire Medical Group

Bedlington

United Kingdom

NE22 6JX

Study participating centre

Laburnum Surgery

Ashington

United Kingdom

NE63 0XX

Study participating centre

Lintonville Medical Group

Lintonville Terrace

Ashington

United Kingdom

NE63 9UT

Sponsor information

Organisation

North Tyneside General Hospital

Sponsor details

Northumbria Healthcare NHS Foundation Trust
Research & Development
Rake Lane
North Shields
England
United Kingdom
NE29 8NH

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/01zy11s57>

Funder(s)**Funder type**

Government

Funder Name

National Osteoporosis Society

Alternative Name(s)

NOS

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Funder Name

National Institute for Health Research

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

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

Intention to publish date

31/08/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from wasim.baqir@nhs.net

IPD sharing plan summary

Data sharing statement to be made available at a later date