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Northumbria osteoporosis project: Group clinics

Submission date	Recruitment status	[ ] Prospectively registered
19/06/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/09/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/10/2017	Musculoskeletal Diseases	[ ] 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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Public

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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.

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.

Intervention Type
Behavioural

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes