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Study of whether radiotherapy after surgery to treat a weakened or broken bone caused by cancer helps to reduce pain and improve quality of life

Submission date
16/10/2025

Recruitment status
Recruiting

Registration date
30/10/2025

Overall study status
Ongoing

Last Edited
30/10/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People with advanced cancers, like breast or prostate cancer, often develop bone problems that can lead to painful fractures. These are called pathological fractures and usually need surgery to fix or replace the damaged bone. After surgery, many patients are given radiotherapy to help with pain and healing. However, there's no strong evidence that this treatment actually helps. Radiotherapy can also cause side effects, delay other treatments, and take up NHS resources. This study aims to find out whether giving radiotherapy after surgery really improves pain and quality of life, or if it's just adding extra burden without enough benefit.

Who can participate?
Adults who are having surgery to treat bone fractures caused by cancer (not including spine surgery) may be able to take part. The study is looking to include 350 people from across the UK.

What does the study involve?
Participants will be randomly placed into one of two groups. One group will receive radiotherapy within 10 weeks after surgery. The other group will not receive radiotherapy during that time but will be monitored closely. If symptoms get worse, radiotherapy may be offered later. Everyone in the study will be followed up for up to 18 months to see how they're doing in terms of pain, quality of life, and other health outcomes.

What are the possible benefits and risks of participating?
Taking part could help researchers understand whether radiotherapy after surgery is truly helpful. This could improve care for future patients. Risks may include side effects from radiotherapy (for those who receive it), and the time and effort involved in attending follow-up appointments and completing questionnaires. Participants may also be offered different types of incentives to help encourage them to stay in the study.

Where is the study run from?
Royal Orthopaedic Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2024 to May 2029

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

Who is the main contact?
Ms Lydia Flett, ytu-portrait@york.ac.uk

Plain English summary under review with external organisation

Contact information

Type(s)
Scientific

Contact name
Ms Lydia Flett

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Type(s)
Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Not applicable

Integrated Research Application System (IRAS)
333375

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 58239, NIHR159676

Study information

Scientific Title
Post-Operative RadioTheRApy In surgically Treated bone metastases (PORTRAIT): a multi-centre, randomised controlled trial

Acronym
PORTRAIT

Study objectives
Primary objective:
To undertake a multi-centre, two-arm, parallel group, RCT to determine whether no immediate radiotherapy (within the first 10 weeks after surgery) is non-inferior to immediate radiotherapy (within the first 10 weeks) following surgery for bone metastases in terms of pain interference measured by the Brief Pain Inventory (BPI) at four months post-randomisation.

Secondary objectives:
1. To undertake a 12-month internal pilot to determine the feasibility of the study, in particular recruitment rate and completeness of follow-up
2. To undertake an analysis of secondary outcomes to assess the impact of radiotherapy on pain interference and severity, quality of life, functional status, survival and rate of re-operation at 4-, 8-, 12-, and up to 18-months post randomisation.
3. To determine the cost-effectiveness of the two treatment options from the NHS perspective to inform the most efficient provision of future NHS care.
4. To undertake a Study within a Trial (SWAT) to evaluate the effectiveness of different types of incentives (cash vs voucher) on participant retention at the primary end point.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/07/2025, North East – Tyne & Wear South Research Ethics Committee (Address: Not available; +44 (0)2071048120, +44 (0)207 104 8286; tyneandwearsouth.rec@hra.nhs.uk), ref: 25/NE/0124

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bone metastases

Interventions
Intervention: No immediate post-operative radiotherapy (within 10 weeks of surgery): Routine clinical monitoring will be undertaken and if patients develop progressive local symptoms radiotherapy may be offered after this period.

Comparator: Immediate post-operative radiotherapy (within 10 weeks of surgery): Delivered using the preferred regimen of the treating Clinical Oncologist 4-10 weeks following surgery.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Pain interference measured using the Brief Pain Inventory (BPI) at 4 months post-randomisation

Key secondary outcome(s))
1. Pain severity is measured using the Brief Pain Inventory (BPI) mean severity score at 4, 8, 12, and approximately 18 months post-randomisation
2. Pain response is measured using the International Consensus Pain Response Endpoints (ICPRE) at 4, 8, 12, and approximately 18 months post-randomisation
3. Quality-adjusted life years are measured using the EQ-5D-5L at 4, 8, 12, and approximately 18 months post-randomisation
4. Patient-reported functional status is measured using the Toronto Extremity Salvage Score (TESS) at 4, 8, 12, and approximately 18 months post-randomisation
5. Overall survival is measured using clinical follow-up data at 4, 8, 12, and approximately 18 months post-randomisation
6. Revision surgical rates are measured using clinical records at 4, 8, 12, and approximately 18 months post-randomisation
7. Time to re-operation is measured using clinical records at 4, 8, 12, and approximately 18 months post-randomisation
8. Re-irradiation for pain is measured using clinical records at 4, 8, 12, and approximately 18 months post-randomisation

9. Time to re-irradiation is measured using clinical records at 4, 8, 12, and approximately 18 months post-randomisation
10. Resource use is measured using health economic data collection tools at 4, 8, 12, and approximately 18 months post-randomisation
11. Cost-effectiveness is measured using health economic modelling based on EQ-5D-5L and resource use data at 4, 8, 12, and approximately 18 months post-randomisation
12. Adverse events are measured using clinical records and patient reports at 4, 8, 12, and approximately 18 months post-randomisation

Completion date
31/05/2029

Eligibility

Key inclusion criteria
Main PORTRAIT trial:
1. The patient is over 18 years old.
2. The patient has had surgery for a pathological fracture or impending fracture due to metastatic bone disease in the long bones of the arms and legs (metastatic carcinoma or myeloma).
3. The patient is able to provide informed consent to take part in the study.

Incentive SWAT
1. Any participant who is due to be sent their four month follow up questionnaire, will be eligible for the incentive SWAT.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Main PORTRAIT trial:
1. Index surgical procedure is undertaken for spinal metastases.
2. Index surgical procedure is a revision of failed previous surgery for metastatic bone disease.
3. Index surgical procedure is for a bone sarcoma or associated metastases.
4. Index surgical procedure is for a known or suspected lymphoma.
5. Patient is undergoing non-surgical management of an impending or pathological fracture (e.g. sling, plaster of Paris).
6. Patient has a life expectancy estimated to be less than 4 months.

7. Patient has had previous radiotherapy targeting the surgically treated bone.
8. Patient is participating in another study evaluating the effectiveness of radiotherapy for treatment of bone metastases.
9. Patient previously participated in the PORTRAIT study.
10. Patient is currently pregnant.

Incentive SWAT:
1. Any participant who has withdrawn from the main PORTRAIT trial will be excluded from the recognition SWAT.

Date of first enrolment
01/09/2025

Date of final enrolment
30/11/2027

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Study participating centre
Royal Orthopaedic Hospital
The Woodlands
Bristol Road South
Northfield
Birmingham
United Kingdom
B31 2AP

Study participating centre
James Cook University Hospital Laboratory
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre

Freeman Road Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Musgrove Park Hospital
Musgrove Park
Taunton
United Kingdom
TA1 5DA

Study participating centre
Countess of Chester Hospital
Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre
Glasgow Royal Infirmary
84 Castle Street
Glasgow

United Kingdom
G4 0SF

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
Belfast City Hospital
51 Lisburn Rd
Belfast
United Kingdom
BT9 7AB

Study participating centre
Nottingham University Hospitals NHS Trust
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Royal Infirmary of Edinburgh at Little France
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
United Kingdom
EH16 4SA

Study participating centre
Walsall Manor Hospital
Moat Road
Walsall
United Kingdom
WS2 9PS

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW

Study participating centre
King's Mill Hospital
Mansfield Road
Sutton-in-ashfield
United Kingdom
NG17 4JL

Study participating centre
Royal Devon & Exeter Hospital (wonford)
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Chapel Allerton Hospital
Chapeltown Road
Leeds
United Kingdom
LS7 4SA

Study participating centre
Northumbria Healthcare NHS Foundation Trust
Unit 7/8, Silver Fox Way
Cobalt Business Park

Newcastle upon Tyne
United Kingdom
NE27 0QJ

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Ayrshire and Arran
Ailsa Hospital
Dalmellington Road
Ayr
United Kingdom
KA6 6AB

Sponsor information

Organisation
Royal Orthopaedic Hospital NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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 (fully anonymised) will be available upon request after the publication of the study. Requests for access to data will be reviewed by the Chief Investigator, York Trials Unit (YTU), and the study Sponsor. Requests should be sent to the relevant contacts listed within this study record. Participants will be informed that information collected about them may be shared anonymously with other researchers and will be asked to consent to this.

IPD sharing plan summary
Available on request

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes