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Quality of life after radiotherapy treatment for patients with non-small cell lung cancer

Submission date
29/07/2024

Recruitment status
Recruiting

Registration date
19/08/2024

Overall study status
Ongoing

Last Edited
08/04/2025

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
Radiotherapy of the chest area is widely used in the treatment of lung cancer. Its use in stage IV NSCLC has evolved across the world based on local experience, as doctors attempt to ease symptoms, maintain/improve quality of life, and prolong survival while minimising side effects. The way this type of radiotherapy is given is based on limited and dated evidence with many variations, and there is a need for new research to figure out the best use of radiotherapy, including timing and dosage.
This new research is also needed because radiotherapy machines and radiotherapy delivery techniques have improved and become more effective. The aims of QUARTZ LUNG are:
- to work out the effect that low-dose radiotherapy to the chest has on symptoms, length and quality of life.
- to assess the side effects and safety of low-dose radiotherapy in the chest area
- to work out the cost-effectiveness of this type of radiotherapy
- to identify potential barriers, evaluate and explain the treatment and outcomes, and highlight issues from a patient, carer, and health care professional's point of view.

Who can participate?
Patients aged 16 years and older, with stage IV NSCLC. Not receiving chemotherapy or other systemic treatments, fit enough to receive low-dose radiotherapy to the chest area and without symptoms requiring immediate radiotherapy. The trial is taking place at approximately 36 NHS sites throughout the UK and aims to enrol a total of 448 participants.

What does the study involve?
Following consent, patients will undergo screening tests to ensure they are eligible. Once screened eligible, patients are randomly allocated to one of the two treatment groups. The two treatment groups are:
Control Arm: supportive and palliative care based on your symptoms
Radiotherapy Arm: supportive and palliative care based on your symptoms AND radiotherapy that will start no later than 3 weeks after allocation.
A patient is just as likely to receive either of the treatment groups. If allocated to the radiotherapy arm, patients will have a radiotherapy planning session with a CT scan.
Patients will attend usual clinic visits, or if unable to attend a member of the research team will

contact them by telephone at weeks 0-2, week 3, week 4, week 5, week 6, week 8, month 3, month 4, month 5, month 6 for study assessments. The study assessments will vary depending on the visit but can include weight, asking about how the patient has been feeling and any health issues, asking about any changes to medication and level of self-care/daily activity /physical ability, and completing questionnaires.

What are the possible benefits and risks of participating?
Possible benefits:
- There may or may not be a direct medical benefit from taking part in the trial.
- This will help to further our knowledge of how to best use radiotherapy for stage IV NSCLC and this may benefit others with the same condition in the future.

Possible risks/disadvantages:
- There may be some unpleasant side effects.
- There could be risks to your child if you become pregnant, or breastfeeding.
- Patients may have a CT scan of their brain during screening but only if it is a standard assessment at the hospital they are being treated in. They will also have a chest/abdomen/pelvis CT scan at screening unless one has been done recently.
- Patients allocated to the radiotherapy arm will have a radiotherapy planning session with a CT scan. This is the standard of care for patients receiving radiotherapy.

CT scans and radiotherapy use ionising radiation that may cause cancer many years or decades after exposure. The chance of cancer being caused by ionising radiation associated with imaging or radiotherapy is very small in these patients.

Where is the study run from?
The Christie NHS Foundation Trust

When is the study starting and how long is it expected to run for?
April 2023 to December 2027

Who is funding the study?
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Who is the main contact?
tourist-quartzlung@soton.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-quality-of-life-after-radiotherapy-for-advanced-non-small-cell-lung-cancer-quartz

Study website
https://www.southampton.ac.uk/ctu/trialportfolio/listof trials/tourist

Contact information

Type(s)
Public, Scientific

Contact name
Ms Siva Saranya

Contact details
Southampton Clinical Trials Unit, MP131, Southampton General Hospital, Tremona Road
Southampton
United Kingdom
SO16 6YD
+44 (0)23 8120 5154
tourist-quartzlung@soton.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
334993

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 62639, NIHR133518, IRAS 334993

Study information

Scientific Title
QUARTZ LUNG: Quality of life after radiotherapy treatment for patients with stage IV non-small cell lung cancer

Acronym
QUARTZ LUNG (TOURIST Platform)

Study objectives
The QUARTZ LUNG trial will test the hypothesis that early low-dose palliative thoracic radiotherapy is clinically effective in health utility for patients with stage IV non-small cell lung cancer.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/05/2024, South Central - Oxford C Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048144, 207 104 8089, 207 104 8271; oxfordc.rec@hra.nhs.uk), ref: 24/SC/0133

Study design
Randomized parallel-group controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Medical and other records, Telephone

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Stage IV non-small cell lung cancer

Interventions
QUARTZ LUNG is a randomised control trial in the TOURIST Platform. Patients may be identified at any point after the diagnosis of stage IV NSCLC by their usual care team. To permit timely randomisation and minimise treatment delays potentially eligible patients should be identified as soon as possible after the diagnosis of stage IV NSCLC is made. Patients eligible for QUARTZ LUNG may not otherwise meet an oncologist and it is therefore crucial that this cohort are identified by their usual care team or at the thoracic multidisciplinary team meeting.

Early low-dose radiotherapy is added as a treatment for patients with stage IV NSCLC who are not receiving systemic treatment. This study seeks to establish the role of low-dose thoracic palliative for this patient population. Patients will be randomised (1:1) to the addition of thoracic radiotherapy to symptomatic palliative care. Once written informed consent has been gained, all screening and baseline procedures have been completed and the patient is confirmed eligible, they will be randomised (1:1) to one of two study arms: Control Arm – symptom-based supportive and palliative care, Radiotherapy Arm - symptom-based supportive and palliative care and radiotherapy. Patients will have equal chances of receiving one of the two arms. There will be either 2 or 5 visits for radiotherapy, depending on the clinician's decision. Radiotherapy will begin as soon as possible after randomisation, no later than 21 days after randomisation.

Patients will be followed up to Month 6, follow-up assessments include:
- weight
- ECOG performance status
- adverse event, toxicity and medication assessment
- quality of life questionnaires
- smoking habits questions

When all patients have completed all of their study visits, survival data will be collected directly from the hospital sites.
An economic evaluation to measure the quality-adjusted life years at 6 months will be performed. A process evaluation using interviews (over the phone or using an online meeting system (eg. Zoom) and a PPI questionnaire to identify issues for implementation from patients, patient carers and Health Care Professionals.
- 15 patients - individual interview
- All patients - PPI QoL questionnaire completion
- 15 patient-carers - individual interview
- 10 Health Care Professionals (across 2 trials in the TOURIST Platform) - individual interview.

Intervention Type
Procedure/Surgery

Primary outcome measure
Health utility measured using EORTC QLU-C10D Area Under the Curve (AUC; using trapezoidal rule) to derive a health utility score per year. Questionnaire completed: Screening/Baseline, week 0-2, week 3, week 4, week 5, week 6, week 8, month 3, month 4, month 5, month 6.

Secondary outcome measures
1. Overall survival - Defined as time from randomisation to death from any cause. Censored at the last follow-up if event-free.
2. Quality of life using EORTC QLQ-C30 and EQ-5D-5L. Questionnaires completed: Screening /Baseline, month 3, month 6.
3. Lung cancer symptoms using EORTC QLQ-LC13. Questionnaires completed: Screening /Baseline, month 3, month 6.
4. Acute and late toxicity as assessed NCI CTCAE v5.0. From informed consent to end of study.

Overall study start date
01/04/2023

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. ≥16 years of age
2. Stage IV NSCLC (radiological diagnosis confirmed at MDT as a minimum)
3. Thoracic disease amenable to radiotherapy
4. Provision of written informed consent
5. For women of childbearing potential: a negative urine or serum pregnancy test within 7 days prior to the randomisation
6. Patients not having systemic treatment
7. ECOG Performance Status 0-3
8. At least T2 and/or N1 disease
9. Fit to receive low-dose palliative radiotherapy according to local guidelines and assessment

Participant type(s)
Patient

Age group
Mixed

Lower age limit
16 Years

Sex
Both

Target number of participants

Planned Sample Size: 448; UK Sample Size: 448

Key exclusion criteria
1. The need for palliative radiotherapy to the thorax prior to randomisation
2. Comorbidities which are considered a contraindication to radiotherapy by the treating clinical team, including interstitial lung disease and active connective tissue disorders
3. History of prior malignant tumours likely to interfere with the protocol treatment or comparisons
4. Leptomeningeal disease
5. Women who are pregnant or breastfeeding
6. Women of child-bearing potential who are not able or unwilling to use a highly effective method of contraception
7. Patients who, in the judgment of the investigator, will be unlikely or unable to comply with the requirements of the protocol
8. Patients receiving systemic therapy for NSCLC
9. Prior treatments for this NSCLC
10. Patients participating in a clinical trial of an investigational medicinal product

Date of first enrolment
24/07/2024

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

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

Study participating centre
Weston Park Hospital
Witham Road
Sheffield
United Kingdom
S10 2SB

Study participating centre
Leighton Hospital
Leighton
Crewe
United Kingdom
CW1 4QJ

Study participating centre
New Cross Hospital
Wolverhampton Rd, Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Royal Devon and Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
The Christie Hospital
550 Wilmslow Road
Manchester
United Kingdom
M20 4BX

Study participating centre
Queen's Hospital
Barking, Havering and Redbridge University Hospitals NHS Trust
Rom Valley Way

Romford, Essex
United Kingdom
RM7 0AG

Study participating centre
Royal Shrewsbury Hospital
Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ

Study participating centre
Clatterbridge Cancer Centre
65 Pembroke PLACE
Liverpool
United Kingdom
L7 8YA

Study participating centre
Colchester Hospital
Turner Road
Colchester
United Kingdom
CO4 5JL

Study participating centre
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
University College London Hospital
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Edinburgh Cancer Centre
Western General Hospital
Lothian
United Kingdom
EH4 2LF

Study participating centre
Dumfries and Galloway Royal Infirmary
Bankend Road
Dumfries
Dumfries and Galloway
United Kingdom
DG1 4AP

Study participating centre
Guy's and St Thomas' Hospital
Guy's and St Thomas' NHS Foundation Trust
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Bristol Haematology and Oncology Centre
Horfield Road
Bristol
United Kingdom
BS2 8ED

Sponsor information

Organisation
The Christie NHS Foundation Trust

Sponsor details
550 Wilmslow Road
Withington
Manchester
England
United Kingdom
M20 4BX
-
the-christie.sponsoredresearch@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.christie.nhs.uk/

ROR
https://ror.org/03v9efr22

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

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

Intention to publish date
31/12/2028

Individual participant data (IPD) sharing plan
The current data-sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date