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RAPID-RT: a study using patients' routine data to improve care

Submission date
27/01/2023

Recruitment status
Recruiting

Registration date
03/04/2023

Overall study status
Ongoing

Last Edited
28/08/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
The 5-year survival of patients with lung cancer is low, with survival often influenced by what other illnesses the patient may have. Radiotherapy is one of the most important ways to treat lung cancer, with high-dose radiation used to kill cancer cells whilst minimising dose to surrounding healthy tissues to limit side effects. However, due to the position of the tumour within the lungs and directly next to the heart and gullet, toxicities do occur.
Standard-of-care radiotherapy treatments are regularly updated to give patients the best possible chance of a cure. These changes are made based on the best evidence from other centres or, if the change is large, tested in a clinical trial over a number of years. However, using a clinical trial for small updates in treatment is impractical. Therefore the RAPID-RT team want to develop and test a new method that will use 'real-world' data, to provide evidence on whether small changes in treatments introduced by the clinical team are having a positive impact on our patient outcomes at the Christie. Real-world data means that the RAPID-RT will only use data that is already collected during a patient's routine treatment and follow-up.
This method will initially be used to look at the impact of a change in the standard of care practice introduced at the Christie for patients receiving radiotherapy for stage I, II and III lung cancer which included the addition of a radiation dose limit to the heart. The radiation dose to the cancer has not changed, but by reducing the radiation dose to the heart, patient survival may increase.
The researchers want to include data from as many patients as possible receiving this new standard of care radiotherapy treatment in the data analysis. This will mean that any changes in patient outcomes that the RAPID-RT team see will represent the range of patients treated at the Christie.

Who can participate?
All patients with stage I, II and III lung cancer aged 18 years and over who are receiving standard-of-care radiotherapy at the Christie NHS Foundation Trust

What does the study involve?
This is a data-only study. There is no change in patient care. Only data that is routinely collected in a patient's electronic health record would be included in the analysis. This data will be anonymised before it is seen by the research team. This data will be used to develop a method

to compare outcomes from patients treated after a change in the standard of care with those treated before the change.

What are the possible benefits and risks of participating?
There are no direct risks or benefits from taking part. No changes in patient care will occur. However, including as many patients' data as possible in the study means the researchers can be more sure that any results they see are accurate. They can use these results to improve care for future patients.

Where is the study run from?
The Christie Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2022 to January 2027

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

Who is the main contact?
rapid-rt@manchester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Rebecca Holley

ORCID ID
https://orcid.org/0000-0003-4150-3299

Contact details
The University of Manchester
c/o The Christie Hospital
Department 58, radiotherapy-related research
Wilmslow Road
Manchester
United Kingdom
M20 4BX
+44 (0)7920196898
Rebecca.holley@manchester.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
317619

Central Portfolio Management System (CPMS)
54782

Study information

Scientific Title
A study to develop the rapid-learning methodology and evaluate its clinical acceptability to monitor clinical outcomes after radiotherapy in lung cancer patients

Acronym
RAPID-RT

Study objectives
The objective of this study is to investigate the practicality and clinical acceptability of using real-world data to measure changes in outcomes following the evolution of standard-of-care practices.

This will be achieved by:
1. Developing a rapid-learning methodology using only real-world data to evaluate patient outcomes following evolutionary changes to standard-of-care radiotherapy for lung cancer delivered at The Christie NHS Foundation Trust.
2. Determining the clinical acceptability of evidence generated by the rapid-learning methodology.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/02/2023, North West - Haydock Research Ethics Committee (3rd Floor - Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071 048032, +44 (0)2071 048248; haydock.rec@hra.nhs.uk), ref: 22/NW/0390

Primary study design
Observational

Study design
Observational; Design type: Cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lung cancer

Interventions
RAPID-RT has been designed to be as inclusive as possible. All patients over the age of 18 with stage I, II or III lung cancer who are undergoing curative-intent non-stereotactic ablative radiotherapy (SABR) radiotherapy treatment are eligible for inclusion. There are no exclusion criteria relating to the upper age limit, comorbidities, or other factors. In consultation with patients and carers the researchers have elected to use an opt-out consent model to reduce the burden on participants, and, they hope, to maximise the number of participants.

'Participation' in RAPID-RT means only that the participant's routine data is pseudo-anonymised and added to the RAPID-RT dataset. Participation does not involve any additional hospital visits, scans, tests, or any other intervention. The RAPID-RT study will be introduced to every eligible patient by the clinical team and patients will be provided with a brief, simple patient information sheet (PIS) that outlines the key points of the study and emphasises the patient's right to opt out of their anonymised data being included in the RAPID-RT analyses. The PIS will also be available as a simple video and a longer video that goes into more detail about the study linked from the PIS and study website. A mark will be made by the clinician on the patient's Christie electronic record to indicate that the PIS has been given to the patient.

Patients may verbally tell their direct care team to exclude their data from RAPID-RT (opt-out) at any time. Alternatively, they can email the team via the email provided on the PIS. An electronic form is available within the Christie electronic record that will be completed only in the case that a patient opts out of the study.

If a patient opts out of the study before they finish their course of radiotherapy, no data will be collected. If they opt out later in their cancer pathway, no further data will be collected and their pseudo-anonymised data will be removed from the RAPID-RT dataset.

If analyses have already taken place on anonymised data pulled from the database, it will not be possible to re-identify this data and remove it. However, data belonging to the patient will be excluded from all future analyses.

Intervention Type
Other

Primary outcome(s)
Assessment of the suitability of real-world data collected in the electronic health care record for patients with lung cancer at the Christie Hospital to evaluate changes in radiotherapy practice during the course of the study

Key secondary outcome(s)
Current secondary outcome measures as of 03/04/2024:

1. Real-world treatment and outcome data extracted from eligible patient clinical notes in pseudo-anonymised form for modelling daily over the course of the study.
2. Quality of real-world data captured in the database (accuracy and completeness) analysed using data curation strategies at monthly intervals over the course of the study.
3. Assessment of changes in patients' outcomes (1-year survival and incidence of grade 3+ oesophagitis or pneumonitis toxicities) following a change in standard of care radiotherapy that initially includes the addition of a dose limit for the top of the heart, assessed using developed statistical methodology as a continual process over course of the study
4. Review of opt-out consent implementation and percentage of patients who decline to include their data in the study at regular intervals over the course of the study. Interviews with patients and the clinical team will be used to look at acceptability of opt-out process.

Previous secondary outcome measures:

1. Real-world treatment and outcome data extracted from eligible patient clinical notes in pseudo-anonymised form for modelling daily over the course of the study.

2. Quality of real-world data captured in the database (accuracy and completeness) analysed using data curation strategies at monthly intervals over the course of the study.
3. Assessment of changes in patients' outcomes (1-year survival and incidence of grade 3+ oesophagitis or pneumonitis toxicities) following a change in standard of care radiotherapy that initially includes the addition of a dose limit for the top of the heart, assessed using developed statistical methodology as a continual process over course of the study
4. Review of opt-out consent implementation and percentage of patients who decline to include their data in the study at regular intervals over the course of the study

Completion date
31/01/2027

Eligibility

Key inclusion criteria
1. Patients diagnosed with stage I, II or III lung cancer (any type)
2. Undergoing curative-intent non-SABR radiotherapy at The Christie Hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Under 18 years of age
2. Patients' data will be excluded from this study if the patient opts out of the study
3. There are no exclusion criteria relating to patient comorbidities, any upper age limit or any other measure

Date of first enrolment
03/04/2023

Date of final enrolment
31/01/2027

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Christie Hospital NHS Foundation Trust

ROR
https://ror.org/03v9efr22

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR202024

Results and Publications

Individual participant data (IPD) sharing plan
The de-identified datasets generated during and/or analysed during the current study are not expected to be made publicly available. Requests to access the fully anonymous analysis datasets should be directed to the Sponsor of the study for consideration and approval in line with The Christie Data Sharing Policy.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		27/08/2025	28/08/2025	Yes	No

HRA research summary			28/06/2023	No	No
Participant information sheet	version 2.0	04/01/2023	14/02/2023	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes