ISRCTN11499979 https://doi.org/10.1186/ISRCTN11499979

Does the planning tool "Multi-Criteria Optimisation (MCO)" reduce the radiation dose received to the chest wall when planning a lung cancer radiotherapy treatment, in comparison to traditional planning methods?

Submission date
08/09/2018

Recruitment status
No longer recruiting

Registration date
25/09/2018

Overall study status
Completed

Last Edited
02/07/2020

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Lung Cancer Stereotactic Ablative Radiotherapy (SABR) is a growing radiotherapy treatment used in the United Kingdom. It is used to precisely target lung cancers. It is only suitable for some people - usually those with smaller cancers - who are unable to have surgery.
SABR uses beams of radiation directed from different angles that centre on the tumour. The tumour is given a high dose of radiation, while the surrounding healthy tissues, such as the chest wall and ribs, receive a low dose. This lowers the risk of damage to healthy tissue surrounding the tumour. This treatment is given in 3-8 treatments.
This service evaluation aims to establish whether current planning methods are producing the best SABR plans, or whether using of the Multi-Criteria Optimisation (MCO) RayStation© planning tool (Raysearch, 2018) would further improve the plans produced by potentially reducing the amount of radiation dose to the patient's chest wall, whilst maintaining adequate dose to the tumour.

Who can participate?
Historical (2015-2018) lung cancer patients' cases, who have been diagnosed with small, T 1-2, non-central lung cancers. Specifically, this includes adult patients within the catchment area of the Dundee Radiotherapy Department who have already been previously planned, and are suitable for SABR.

What does the study involve?
This project will assess the radiotherapy planning CT data of historical lung cancer patients, who have already consented to their originally planned radiotherapy treatment and will not be receiving a new or different treatment from what was originally approved of by the clinician. Each original historical SABR plan will be evaluated and then re-planned, using the MCO planning tool. The MCO plan will be assessed against the Departmental Planning Protocol, considering

the radiation dose covering the tumour and the chest wall radiation dose. The original plan and MCO plans will be compared and evaluated.

What are the possible benefits and risks of participating?
As the study is evaluating historical data, there will be no direct benefits or risks to the patient cases included in this project. However, the results of this evaluation will enable the investigator to establish if improvements can be made to the current planning methods for this patient group in the future. This may potentially result in a reduction to the chest wall of SABR patients, reducing the risk of chest wall pain and rib fractures.

Where is the study run from?
Ninewells Radiotherapy Department, Dundee (UK)

When is the study starting and how long is it expected to run for?
February 2018 to October 2019

Who is funding the study?
NHS Tayside (UK)

Who is the main contact?
Laura Ferguson
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
110818 VN

Study information

Scientific Title
Does Multi-Criteria Optimisation (MCO) for Lung Stereotactic Ablative Radiotherapy (SABR) planning further reduce the dose received to the chest wall whilst maintaining adequate planning target volume (PTV) coverage, in comparison to current practice?

Acronym
MCO SABR

Study objectives
Hypothesis (H1): Using Multi-Criteria Optimisation (MCO) further reduces the chest wall dose received whilst maintaining adequate planning target volume (PTV) coverage.
Null Hypothesis (H0): Using MCO does not further reduce the Chest Wall dose received but maintains an adequate PTV coverage.
Alternative Hypothesis (Ha): Using MCO does further reduce the Chest Wall dose received but compromises on PTV coverage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval is to be obtained from NHS Tayside R&D in September 2018.

Study design
Interventional single-centre service evaluation

Primary study design
Interventional

Secondary study design
Database analysis

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Historical T 1-2 peripheral lung cancer

Interventions
Comparing the current, traditional planning method of optimising Lung Stereotactic-Ablative Radiotherapy (SABR) cancer, against an advanced optimisation method, Multi-Criteria Optimisation (MCO). Lung SABR treatment is a high dose, low fractionation Radiotherapy regime offered to eligible patients that meet a strict criteria, who may otherwise be unsuitable for surgery.
Due to the difficultly in recruiting the specific patients required and the time constraints for

completing this service evaluation, a retrospective cohort design will be used. All potential historical patient CT data sets will be identified by the Investigator CI through the Treatment Planning Software (TPS), following the Lung SABR tag within the system using the selection criteria. If possible, the simple random selection method of sampling to extract patients from this pool will be used. This would include patients that have either historically received SABR treatment or have had SABR contours historically delineated before the implementation of SABR (pre-SABR) adhering to the Departmental Protocol.
An aim of this project is to investigate if the plans produced by traditional optimisation methods can be further improved, specifically, with regards to reducing the radiation dose to the chest wall, by using MCO. This is to ensure that patients are receiving the best quality plans possible. The potential foreseen benefits of using MCO SABR Planning include, the patient receiving less radiation dose to the chest wall, which may reduce the risk of possible side effects including chest wall pain, rib fractures and skin reactions.
This project will specifically assess the radiotherapy planning CT data of historical lung cancer patients, who have already consented to their originally planned Radiotherapy treatment and will not be receiving a new or different treatment from what was originally approved of by the clinician.
Each historical case would be re-planned, using MCO and evaluated with the Departmental Protocol, assessing tumour coverage and chest wall dose. Applicable statistical testing applied. The original and MCO plans compared and evaluated.
All patient data will be anonymised and duplicated within a separate training area of the Treatment Planning Software (TPS).
This service evaluation is part of a Dissertation Masters (MSc) Module in Radiotherapy Planning and will take one year to complete.

Intervention Type
Other

Primary outcome measure
Amount of radiation dose (Gy) that the chest wall receives in the radiotherapy plans. The baseline, or comparison measurement, will be the traditionally optimised radiotherapy plan. The traditionally optimised plan will be planned first and then the MCO optimised plan will be computed on the same day. A delayed timepoint is not required as the same planning CT scan and data will be used for each patient case, it is just the method of optimising the plan that differs.

Secondary outcome measures
The following will be assessed through recording the time taken for each plan, along with observations regarding the ease and/or any difficulties encountered with MCO optimisation, whilst planning each case:
1. Reducing the need for manual in-put of the planner
2. Improve the speed with which plans are produced
3. Aid in the training of staff in Lung Cancer Stereotactic Ablative Radiotherapy (SABR) planning

Overall study start date
01/02/2018

Completion date
01/09/2019

Eligibility

Key inclusion criteria
1. Historical patients (2015-2018)
2. T 1-2 peripheral lung cancer patient
3. Within geographical catchment area of the Radiotherapy Department
4. Aged over 18 years old
5. Already been previously planned, and are deemed suitable for SABR
6. Pathologically confirmed non-small cell lung cancer (NSCLC). If biopsy deemed unsafe, enhancing lesion on FDG PET with radiological characteristics in keeping with NSCLC
7. Patient deemed by MDM as medically unfit for surgery or has declined surgery (WHO PS 0-2)
8. Lesion ≤5 cm with no pathologically enlarged lymph nodes or distant metastases. Mediastinal staging with EBUS should be considered in patients with enlarged or PET equivocal tumours.
9. Lesion >2 cm from main bronchi, oesophagus and the major blood vessels
10. No absolute constraints for FEV1 or DLCO, but patients with interstitial lung disease or established lung fibrosis should be treated with caution

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15

Key exclusion criteria
1. Not deemed suitable for SABR
2. Previously planned
3. NSCLC patients with T2 or T3 primary tumours >5 cm.
4. Metastatic (including to lymph nodes) lung cancer
5. Any tumour that is not clinically definable on the treatment planning CT scan e.g. surrounded by consolidation or atelectasis
6. Tumours within 2 cm radius of main airways and proximal bronchial tree
7. Previous radiotherapy within the planned treatment volume
8. Presence of pulmonary fibrosis (unless the increased risk of SABR has been fully considered and the patient has been appropriately consented)
9. Chemotherapy administered within 6 weeks prior to study entry or planned for <6 weeks following SABR
10. Pregnant or lactating females
If tumour has respiratory motion ≥1 cm, only proceed with treatment if target delineation is reliable and suggested normal tissue and tumour planning constraints can be achieved.

Date of first enrolment
01/10/2018

Date of final enrolment
26/01/2019

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
NHS Tayside Radiotherapy Department
Level 2,
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Sponsor information

Organisation
NHS Tayside

Sponsor details
TASC
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Sponsor type
Research organisation

Website
www.tasc-research.org/industry

ROR
https://ror.org/000ywep40

Funder(s)

Funder type
Not defined

Funder Name
NHS Tayside

Results and Publications

Publication and dissemination plan
The report will be made available for a recognised Radiotherapy peer review journal.

Intention to publish date
01/01/2020

Individual participant data (IPD) sharing plan
As historical patient CT data is being used for this service evaluation, which in will no way affect how patients are currently treated, this research will not be shared with patients.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		02/07/2020	02/07/2020	No	No