

Surgical and large bore pleural procedures in malignant pleural mesothelioma and radiotherapy trial

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
28/10/2011	No longer recruiting	<input checked="" type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
28/10/2011	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
26/10/2022	Cancer	

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-radiotherapy-prevent-spread-mesothelioma-after-chest-wall-operation-smart-trial>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

11023

Study information

Scientific Title

Surgical and large bore pleural procedures in malignant pleural Mesothelioma And Radiotherapy Trial (SMART trial): a randomised controlled trial evaluating whether prophylactic radiotherapy reduces the incidence of procedure tract metastases

Acronym

SMART

Study objectives

Malignant pleural mesothelioma (MPM) is a fatal primary tumour of the pleura and the UK incidence continues to rise. Patients often undergo multiple pleural procedures in order to obtain a diagnosis. Unfortunately there is a risk of tumour seeding along the procedure tracts and subsequent development of painful tract metastases, which can be very difficult to treat.

Prophylactic radiotherapy has been used for many years with a view to preventing procedure tract metastases, however the results of recent research have questioned its benefit. Prophylactic radiotherapy involves several hospital attendances for patients at a time soon after their diagnosis, which can impact negatively on the patients quality of life at this difficult time.

Recent evidence suggests that the patients at highest risk of developing procedure tract metastases (PTM) are those who have undergone larger thoracic incisions, such as surgical procedures or large bore chest drain insertions. This randomised controlled trial endeavours to identify the optimal timing of chest wall radiotherapy in this patient group and examine its effectiveness.

This robust multicentre study will randomise 203 patients with confirmed MPM who have undergone a large bore thoracic procedure to receive immediate (prophylactic) radiotherapy or deferred radiotherapy should they develop a PTM. Patients will be carefully followed up for the development of PTM and quality of life measures and pain scores will be evaluated. By so doing, we hope to answer the heavily debated question about the role and optimal timing of prophylactic radiotherapy in malignant pleural mesothelioma.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee South Central- Southampton B, First MREC approval date 21/09/2011, ref:11/SC/0408

Study design

Randomised; Interventional; Design type: Prevention

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network, Respiratory; Subtopic: Lung Cancer, Respiratory (all Subtopics); Disease: Mesothelioma, Respiratory

Interventions

Patients will be randomised 1:1 to receive either immediate radiotherapy (21Gy in 3 fractions over 3 days) to the pleural procedure site at trial entry, or deferred radiotherapy in the event that they develop a procedure tract metastasis.

Follow Up Length: 12 month(s); Study Entry: Single Randomisation only

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

The incidence of development of PTM around the site of pleural intervention; Timepoint(s): 12 months

Key secondary outcome(s)

1. The effect of prophylactic radiotherapy on the time to PTM development.; Timepoint(s): 12 months
2. Analgesia requirements; Timepoint(s): months 1, 3, 6 ,9, 12
3. Health economics; Timepoint(s): 12 months
4. Identification of emergent themes from the semi-structured qualitative interviews; Timepoint (s): 6 months
5. Monthly chest wall pain score; Timepoint(s): monthly
6. Proportion of PTMs which are painful; Timepoint(s): 12 months
7. Self reported quality of life status; Timepoint(s): 1, 3, 6, 9, 12 months
8. The effect of chemotherapy on the development of PTM; Timepoint(s): 12 months
9. The effect of prophylactic radiotherapy on the severity of PTM when they develop; Timepoint (s): 12 months
10. The incidence of PTM in the context of indwelling pleural catheters; Timepoint(s): 12 months
11. The rate and severity of radiotherapy toxicity; Timepoint(s): 12 months

Completion date

01/08/2014

Eligibility

Key inclusion criteria

1. A histocytologically proven diagnosis of mesothelioma, as confirmed by a multi-disciplinary team (MDT) meeting
2. One of the following pleural interventions in the past 28 days:
 - 2.1. Open pleural biopsy
 - 2.2. Surgical thoracotomy or Video-assisted thoracoscopic surgery (VATS)
 - 2.3. Local anaesthetic thoracoscopy
 - 2.4. Large bore chest tube insertion (greater or equal to 20 Fr inserted by either a seldinger technique or blunt dissection)
 - 2.5. Indwelling pleural catheter insertion
3. Written informed consent

Target Gender: Male & Female ; Lower Age Limit 18 no age limit or unit specified

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

203

Key exclusion criteria

1. Age <18 years
2. Expected survival <4 months
3. Pregnancy or lactation
4. Inability to give informed consent or comply with the protocol
5. Previous radiotherapy which would result in an unacceptable overlap with the proposed treatment field
6. The patient does not have access to a telephone
7. A clinically palpable nodule of at least 1cm diameter felt within 7cm of the margins of the procedure site at the initial trial visit

Date of first enrolment

01/11/2011

Date of final enrolment

01/08/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Southmead Hospital

Bristol

United Kingdom

BS10 5NB

Sponsor information

Organisation

North Bristol NHS Trust (UK)

ROR

<https://ror.org/036x6gt55>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB)

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

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2016		Yes	No

<u>Results article</u>	results	05/02/2018	Yes	No
<u>Protocol article</u>	protocol	09/01/2015	Yes	No
<u>Participant information sheet</u>	Participant information sheet	11/11/2025	11/11/2025	No
<u>Plain English results</u>		26/10/2022	No	Yes