ISRCTN72767336 https://doi.org/10.1186/ISRCTN72767336

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

| | | |
|---|---|---|
| **Submission date**<br>28/10/2011 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>28/10/2011 | **Overall study status**<br>Completed | |
| **Last Edited**<br>26/10/2022 | **Condition category**<br>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**
Dr Amelia Dunscombe

**Contact details**
Southmead Hospital
Southmead Road
Westbury-On-Trym
Bristol
United Kingdom
BS10 5NB
-
Amelia.Dunscombe@nbt.nhs.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
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

### Secondary study design

Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

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

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

## Secondary outcome measures
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

## Overall study start date
01/11/2011

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 203; UK Sample Size: 203

### 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**
England

United Kingdom

**Study participating centre**
**Southmead Hospital**
Bristol
United Kingdom
BS10 5NB

# Sponsor information

**Organisation**
North Bristol NHS Trust (UK)

**Sponsor details**
Dept of Anaesthesia
Southmead Hospital
Southmead Road Westbury-On-Trym
Bristol
England
United Kingdom
BS10 5NB

**Sponsor type**
Hospital/treatment centre

**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

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 09/01/2015 | | Yes | No |
| Results article | results | 01/08/2016 | | Yes | No |
| Results article | results | 05/02/2018 | | Yes | No |
| Plain English results | | | 26/10/2022 | No | Yes |