

# Symptom Study of radioThErapy in MeSothelioma

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>17/05/2012   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>03/08/2012 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>25/01/2022       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-study-find-out-radiotherapy-help-control-pain-people-mesothelioma>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

SYSTEMS2012

## Study information

Scientific Title

# A single arm observational SYmptom Study of radioThErapy in MeSothelioma

## Acronym

SYSTEMS

## Study objectives

The aim of the SYSTEMS study is to assess the effect of radiotherapy on key symptoms in patients with mesothelioma (e.g. pain) using comprehensive and validated symptom assessment measures.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Primary study design

Observational

## Study design

Single-arm phase II observational study

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Malignant pleural mesothelioma (MPM)

## Interventions

The symptoms will be measured using validated questionnaires at end of radiotherapy treatment (week 1), at week 5 and week 12 (final study visit)

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome(s)

This research will assess if radiotherapy is beneficial in treating pain in malignant pleural mesothelioma (MPM).

## Key secondary outcome(s)

1. To assess whether radiotherapy improves other symptoms (dyspnoea, fatigue, distress) using a number of validated questionnaires
2. Possible biomarkers will be examined and the relationship between inflammation and symptoms explored

## Completion date

15/12/2013

# Eligibility

## Key inclusion criteria

1.  $\geq 18$  years of age.
2. Histological or multi-disciplinary team (MDT) diagnosis of mesothelioma
3. Able to complete study assessments
3. Life expectancy of at least 3 months based on clinical judgement
4. Due to receive radiotherapy for pain resulting from mesothelioma (defined as index site site of radiotherapy)
5. Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2
6. CT scan within 6 weeks of radiotherapy
7. Worst pain  $>4/10$  (0-10 Visual Analogue Scale) corresponding to the index site

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 Years

## Sex

All

## Total final enrolment

40

## Key exclusion criteria

1. Received chemotherapy or radiotherapy in the preceding six weeks that is likely to alter pain at the index site during the duration of the study
2. Planned chemotherapy during the period of the study that is likely to alter pain during the course of the study
3. Psychotic disorders or cognitive impairment
4. Co-existing lung tumours at the time of study entry
5. Pregnant or breastfeeding

## Date of first enrolment

14/06/2012

## Date of final enrolment

15/12/2013

# Locations

## Countries of recruitment

United Kingdom

Scotland

**Study participating centre**  
**Western General Hospital**  
Edinburgh  
United Kingdom  
EH4 2XR

## Sponsor information

**Organisation**  
NHS Greater Glasgow and Clyde (UK)

**ROR**  
<https://ror.org/05kdz4d87>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
June Hancock Mesothelioma Research Fund (UK)

**Funder Name**  
Bestson Oncology Fund (UK)

## 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? |
|-------------|---------|--------------|------------|----------------|-----------------|
|-------------|---------|--------------|------------|----------------|-----------------|

|                                       |         |            |            |     |     |
|---------------------------------------|---------|------------|------------|-----|-----|
| <a href="#">Results article</a>       | results | 01/06/2015 |            | Yes | No  |
| <a href="#">Results article</a>       | results | 01/11/2016 |            | Yes | No  |
| <a href="#">Plain English results</a> |         | 04/09/2015 | 25/01/2022 | No  | Yes |