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SYmptom Study of radioThErapy in MeSothelioma

Submission date	Recruitment status	[_] Prospectively registered
17/05/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/08/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/01/2022	Cancer	

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

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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

Study design
Single-arm phase II observational study

Primary study design
Observational

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. >/=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?

Results article	results	01/06/2015		Yes	No
Results article	results	01/11/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results		04/09/2015	25/01/2022	No	Yes