ISRCTN10644347 https://doi.org/10.1186/ISRCTN10644347

SYmptom Study of radioThErapy in MeSothelioma

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

Contact name
Dr Barry Laird

Contact details
Institute of Genetics and Molecular Medicine
Edinburgh Cancer Research UK Centre
Western General Hospital
Crewe Road
Edinburgh
United Kingdom
EH4 2XR
+44 (0)131 777 3548
barry.laird@ed.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Other

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

Secondary outcome measures
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

Overall study start date
14/06/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
42

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
Scotland

United Kingdom

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

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

Sponsor details
c/o Nathaniel Brittian
R&D Central Office, Tennent Institute, 1st Floor
Western Infirmary General
38 Church Street
Glasgow
Scotland
United Kingdom
G11 6NT
+44 (0)141 211 8544
nathaniel.brittian@ggc.scot.nhs.uk

Sponsor type

Hospital/treatment centre

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

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?
Results article	results	01/06/2015		Yes	No
Results article	results	01/11/2016		Yes	No
Plain English results		04/09/2015	25/01/2022	No	Yes