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SYSTEMS 2: a randomised phase II trial of standard versus dose escalated radiotherapy in the treatment of pain in malignant pleural mesothelioma

Submission date 05/11/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 05/11/2015	**Overall study status** Completed	
Last Edited 30/05/2025	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-higher-dose-radiotherapy-to-treat-pain-caused-by-mesothelioma-systems-2

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Sponsor ref: GN13ON388

Study information

Scientific Title
A multicentre phase II randomised dose escalation study comparing two schedules of hypo-fractionated radiotherapy: 36 Gy in 6# over two weeks (treatment arm) and 20 Gy in 5# over one week (standard arm)

Acronym
SYSTEMS-2

Study objectives
To establish whether dose escalated, hypo-fractionated radiotherapy (36 Gray in 6 fractions) increases the proportion of malignant pleural mesothelioma (MPM) patients experiencing a clinically significant improvement in pain at 5 weeks compared with standard radiotherapy (20 Gray in 5 fractions)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre Phase II randomised study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Malignant pleural mesothelioma (MPM)

Interventions
Patients who are due to receive radiotherapy for the treatment of pain due to MPM will be eligible for the study. Patients will be randomised to one of two arms:
1. Standard Treatment: Patients randomised to receive standard radiotherapy will receive 20 Gray of radiotherapy, which will be given in 5 doses. Patients will receive one treatment per day for one week (Monday to Friday)
2. Dose Escalated Treatment: Patients randomised to receive dose escalated radiotherapy will receive 36 Gray of radiotherapy, which will be given in 6 doses. Patients will receive a dose on alternate days over 2 weeks. For patients with large volume disease or where there is a risk of severe acute toxicity there will be the option of reducing dose to 30 Gy in 5 fractions

Intervention Type
Procedure/Surgery

Primary outcome(s)
Establish whether dose escalated, hypo-fractionated radiotherapy (36 Gy in 6#) increases the proportion of MPM patients experiencing a clinically significant improvement in pain at 5 weeks compared with standard radiotherapy (20 Gy in 5#)

Key secondary outcome(s))
Determine the relative effects of dose escalated and standard radiotherapy on:
1. Acute toxicity at weeks 5 and 9
2. Pain response at week 5 and 9 (BPI)
3. Radiological response at week 9, measured by CT scan reported to modified RECIST
4. Overall survival
5. Quality of life at weeks 5 and 9 (EORTC QLQ-C30)

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Histological and/or MDT diagnosis of MPM
2. Performance status 0-2 (ECOG)
3. Predicted life expectancy of >12 weeks
4. CT scan within 8 weeks of radiotherapy
5. Worst Pain ≥4/10 (0-10 Numerical Rating Scale) after optimisation of analgesics
6. Ability to provide written informed consent prior to participating in the trial and any trial related procedures being performed
7. Willingness to comply with scheduled visits, treatment plans and laboratory tests and other study procedures
8. Patients must have a radiotherapy plan compatible with both the standard arm (20 Gy in 5 fractions) and treatment arm (30-36 Gy in 5-6 fractions)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients who have received anti-cancer therapy within the 4 weeks prior to study entry that is likely to alter pain at the index site during the duration of the study
2. Patients who are planned to have further anti-cancer therapy within 6 weeks post

radiotherapy treatment
3. Psychotic disorders or cognitive impairment
4. Co-existing lung tumours at the time of study entry
5. Pregnant or breastfeeding
6. Patients of child-bearing potential, who are unwilling to use 2 effective methods of contraception

Date of first enrolment
01/03/2016

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Beatson West of Scotland Cancer Centre
1053 Great Western Road
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Study participating centre
The Royal Marsden Hospital
London
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Study participating centre
Nottingham City Hospital
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NG5 1PB

Study participating centre
Weston Park Hospital
Sheffield
United Kingdom
S10 2SJ

Study participating centre
Plymouth Oncology Centre
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Velindre Cancer Centre
Velindre
United Kingdom
CF14 2TL

Study participating centre
Christie NHS Foundation Trust
Manchester
United Kingdom
M20 4BX

Study participating centre
Belfast City Hospital
Belfast
United Kingdom
BT9 7AB

Study participating centre
Addenbrookes Hospital
Cambridge
United Kingdom
CB2 0QQ

Study participating centre

Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Study participating centre
Royal Preston Hospital
Preston
United Kingdom
PR2 9HT

Study participating centre
St. James's Institute of Oncology
Leeds
United Kingdom
LS9 7BE

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

ROR
https://ror.org/05kdz4d87

Organisation
University of Glasgow

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
Charity

Funder Name
June Hancock Mesothelioma Research Fund

Alternative Name(s)
JHMRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Beatson Cancer Charity

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			30/05/2025	No	Yes