ISRCTN12698107 https://doi.org/10.1186/ISRCTN12698107

# 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

**Registration date**
05/11/2015

**Overall study status**
Completed

**Last Edited**
30/05/2025

**Condition category**
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

**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

**Contact name**
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## Additional identifiers

**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
Glasgow
United Kingdom
G12 0YN

### Study participating centre
**The Royal Marsden Hospital**
London
United Kingdom
SW3 6JJ

### Study participating centre
**Nottingham City Hospital**
Nottingham
United Kingdom
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? |
|---|---|---|---|---|---|
| Plain English results | | | 30/05/2025 | No | Yes |