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

Submission date	Recruitment status	[X] Prospectively registered
05/11/2015	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
05/11/2015	Completed	Results
Last Edited	Condition category	Individual participant data
30/05/2025	Cancer	[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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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Sponsor ref: GN13ON388

Study information

Scientific Title

A multicentre phase II randomised dose escalation study comparing two schedules of hypofractionated 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

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 measure

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#)

Secondary outcome measures

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)

Overall study start date

01/03/2016

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

Age group

Adult

Sex

Both

Target number of participants

112

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

England

Northern Ireland

Scotland

United Kingdom

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

Sponsor details

Research and Development Central Office The Tennent Institute, 1st Floor Western Infirmary General 38 Church Street Glasgow Scotland United Kingdom G11 6NT

Sponsor type

Hospital/treatment centre

Website

http://www.nhsggc.org.uk/

ROR

https://ror.org/05kdz4d87

Organisation

University of Glasgow

Sponsor details

Clinical Trials Unit 1st Floor Tennent Building 38 Church Street Western Infirmary Glasgow Scotland United Kingdom G11 6NT

Sponsor type

University/education

Website

http://www.gla.ac.uk/

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

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Plain English results30/05/2025NoYes