Prophylactic Irradiation of Tracts in mesothelioma

Submission date	Recruitment status Stopped	[X] Prospectively registered		
17/05/2012		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/05/2012	Stopped Condition category	Results		
Last Edited		Individual participant data		
21/06/2019	Cancer	Record updated in last year		

Plain English summary of protocol

http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-type-radiotherapy-called-pit-people-tests-lung-cancer-called-mesothelioma-pit

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT01604005

Secondary identifying numbers

Study information

Scientific Title

A phase III randomised trial of prophylactic irradiation of tracts in patients with malignant pleural mesothelioma following invasive chest wall intervention

Acronym

PIT

Study objectives

The PIT (Prophylactic Irradiation of Tracts) trial will determine the efficacy, as assessed by the incidence of chest wall metastasis, of PIT following invasive chest wall intervention in malignant pleural mesothelioma compared to no prophylactic radiotherapy.

Patients will be randomised on a 1:1 basis to receive PIT or No PIT. The trial is a phase III multicentre trial that aims to recruit 374 patients across the UK.

After randomisation PIT patients will receive 21 Gy over 3 fractions. All patients will be followed up for a total of 52 weeks with regular clinic visits and then followed up over the phone.

The primary endpoint is Incidence of chest wall tract metastasis 6 months from randomisation. The secondary endpoints are: time from randomisation to chest wall metastasis; position of metastasis in relation to radiation field for PIT patients; acute and late skin toxicity for PIT patients; and pain from chest wall metastasis evaluated using the Visual Analogue Scale (VAS) pain score

Ethics approval required

Old ethics approval format

Ethics approval(s)

Greater Manchester West Ethics Committee, 04/04/2012, ref: 12/NW/0249

Study design

Randomised interventional prevention trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

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

Lung Cancer, Mesothelioma

Interventions

Patients who meet the eligibility criteria will be randomised to PIT or No PIT. The PIT patients will receive radiotherapy at 21 Gy in 3 fractions to the intervention (surgery) site. Chemotherapy on both arms is optional. Follow up is for 2 years on both arms (or until chest wall recurrence or death) and includes regular telephone follow up and for the first year patients coming in to the hospital regularly as outpatients.

Intervention Type

Other

Phase

Phase III

Primary outcome measure

Efficacy as assessed by the incidence of chest wall metastasis

Secondary outcome measures

- 1. Toxicity of PIT
- 2. Time to chest wall metastasis in patients undergoing PIT as compared to no radiotherapy
- 3. Pain from chest wall metastasis

Overall study start date

30/05/2012

Completion date

30/06/2015

Eligibility

Key inclusion criteria

- 1. Either sex, age = 18 year
- 2. Diagnosis of mesothelioma by MDT
- 3. All histological subtypes. Where the histological diagnosis is unclear, a specialist thoracic pathologist should be consulted.
- 4. ECOG performance status 0-2.
- 5. Inoperable disease or operable disease in patients unsuitable for surgery as decided by a MDT.
- 6. Chest wall intervention with video-assisted thoracoscopy (VATS), open surgical biopsy, local anaesthetic thoracoscopy or chest drain.
- 7. Able to start radiotherapy within 42 days (6 weeks) from most recent chest wall intervention.
- 8. Chest wall intervention scar visible at time of randomisation.
- 9. No indwelling pleural catheters in-situ at the intervention site
- 10. RT target volume acceptable by the local radiotherapist.
- 11. No previous open thoracotomy.
- 12. No previous radiotherapy to the region of the chest wall intervention site.

- 13. Not currently receiving chemotherapy and not received chemotherapy for mesothelioma before randomisation
- 14. No other previous or concomitant illness or treatment which in the opinion of the clinician will interfere with the trial treatments or comparisons.
- 15. Patients enrolled on other clinical trials could be considered after discussion with the chief investigators.
- 16. Female patients must satisfy the investigator that they are not pregnant, or are not of childbearing potential, or are using adequate contraception.
- 17. Patients must not be breastfeeding
- 18. Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the trial protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial
- 19. Before patient registration/randomisation, written informed consent must be given according to ICH/GCP, and national/local regulations.
- 20. Patients can only be randomised in this trial once.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 374; UK Sample Size: 374

Key exclusion criteria

- 1. Patients who underwent a thoracotomy (as large thoracotomy scars may not be adequately covered by this radiotherapy technique)
- 2. Previous radiotherapy to the region of the chest wall intervention site
- 3. Patients currently receiving chemotherapy

Date of first enrolment

30/05/2012

Date of final enrolment

30/06/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre The Christie NHS Foundation Trust

Manchester United Kingdom M20 4BX

Sponsor information

Organisation

Christie Hospital NHS Foundation Trust (UK)

Sponsor details

550 Wilmslow Road Manchester England United Kingdom M20 4BX

Sponsor type

Hospital/treatment centre

Website

http://www.christie.nhs.uk/

ROR

https://ror.org/03v9efr22

Funder(s)

Funder type

Government

Funder Name

Research for Patient Benefit Programme

Alternative Name(s)

NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type

Government organisation

Funding Body Subtype

National government

LocationUnited Kingdom

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date 31/12/2016

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?
Protocol article	protocol	27/01/2016		Yes	No