ISRCTN04240319 https://doi.org/10.1186/ISRCTN04240319

Prophylactic Irradiation of Tracts in mesothelioma

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

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
Mr Colin Lunt

Contact details
Clinical Trials Co-ordination Unit
The Christie NHS Foundation Trust
Wilmslow Road
Manchester
United Kingdom
M20 4BX
+44 (0)161 918 7492
colin.lunt@christie.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01604005

Secondary identifying numbers

12213

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 multi-centre 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

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not 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