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Mesothelioma And Radical Surgery

Submission date 28/05/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/07/2004	**Overall study status** Completed	
Last Edited 18/10/2018	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
This study was designed to investigate the effectiveness of a form of major surgery known as extra pleural pneumonectomy (EPP) for patients diagnosed with malignant pleural mesothelioma (a malignant tumour involving the lining of the lung). The benefits considered were longer survival and/or improved quality of life.
Mesothelioma surgery is usually accompanied by chemotherapy and, where appropriate, it is followed by radiotherapy. Because the available knowledge on patients outcome was from those who had received all three forms of cancer treatment as a package (chemotherapy, surgery and radiotherapy), it was not possible to determine from the existing evidence whether the surgical component itself was helpful to them.

Who can participate?
Patients 18 years of age or older with pleural mesothelioma, considered suitable for these treatments based on the knowledge available in the early 2000s when the study was being planned, were asked to give written consent to join the study.

What does the study involve?
Participants were given chemotherapy and then had further tests. Their response to chemotherapy and the results of the tests were reviewed by a team of medical specialists. Patients assessed as suitable (in terms of their general health and the extent of the cancer) were invited to consent to be randomly allocated to have EPP surgery, followed by radiotherapy, or to not have EPP surgery.

What are the possible benefits and risks of participating?
Not provided.

Where is the study run from?
The study was conducted in 12 hospitals located throughout the UK. The Clinical Trials and Statistics Unit at The Institute of Cancer Research co-ordinated the study.

When is the study starting and how long is it expected to run for?
The study ran from July 2006 to July 2009.

Who is funding the study?
Cancer Research UK and the June Hancock Mesothelioma Fund.

Who is the main contact?
Professor Tom Treasure
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Contact information

Type(s)
Scientific

Contact name
Prof Tom Treasure

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00253409

Secondary identifying numbers
N/A

Study information

Scientific Title
Mesothelioma And Radical Surgery

Acronym
MARS

Study objectives
Added 06/08/09:
To determine whether 50 malignant mesothelioma patients can be randomised to radical surgery versus best palliative care within a year. It will also determine the effects of surgery on survival and quality of life and provided that recruitment & safety data are acceptable, it will be extended to an international randomised trial with the aim of providing definitive data on the

value of Extra-Pleural Pneumonectomy (EPP) surgery in the treatment of early stage malignant mesothelioma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Mesothelioma

Interventions
Prior to randomisation all patients undergo 3 cycles of cisplatin based chemotherapy. Randomisation arms are with or without extrapleural pneumonectomy (EPP) surgical intervention. Those with EPP will go on to have radical radiotherapy.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
05/07/2006

Completion date

05/07/2009

Eligibility

Key inclusion criteria
Two phase eligibility:

Registration Eligibility criteria at registration:
1. 18 years of age or older
2. Histologically proven mesothelioma
3. Fit to undergo extrapleural pneumonectomy (EPP) as per British Thoracic Society (BTS) guidelines
4. Fit to undergo the planned post-operative radiotherapy
5. Able to complete Quality of Life questionnaires
6. Able to comply with follow-up requirements
7. Written informed consent for registration
8. Positron emission tomography (PET) or mediastinoscopy negative
9. No distant metastases

Once chemotherapy has been completed a further eligibility criteria is checked to determine continued eligibility for randomisation.
Eligibility criteria for randomisation:
1. Still fulfil eligibility criteria for registration
2. Completion of 3 cycles of chemotherapy
3. Operable disease (T1-3, N0-1, M0)
4. Biopsy proven malignant mesothelioma on histology and immuno-histochemistry
5. Normal renal function
6. World Health Organisation (WHO) performance status 0 or 1
7. Written informed consent for randomisation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
100 (50 in each arm) (Added 06/09/2011: 50 patients in total randomised to the Feasibility Study)

Key exclusion criteria
1. Predicted post-operative forced expiratory volume in 1 second (FEV1) of less than 40% and carbon monoxide transfer factor (TLCO) of less than 40%
2. Significant pulmonary hypertension
3. Cardiac ejection fraction of less than 40%

Date of first enrolment
05/07/2006

Date of final enrolment
05/07/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Operation Research Unit
London
United Kingdom
WC1H 0BT

Sponsor information

Organisation
Guy's and St. Thomas' Hospitals NHS Foundation Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (Reference number C150 / A3889)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
June Hancock Mesothelioma Research Foundation (No reference number given)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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				No	Yes
Protocol article	protocol	01/02/2006		Yes	No
Results article	results	01/10/2009		Yes	No
Results article	results	01/08/2011		Yes	No