ISRCTN54469112 https://doi.org/10.1186/ISRCTN54469112

Medical Research Council (MRC)/British Thoracic Society (BTS) phase II feasibility trial of the management of mesothelioma

Submission date 21/09/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/09/2000	**Overall study status** Completed	
Last Edited 29/10/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ctu.mrc.ac.uk/studies/MESO_1.asp

Contact information

Type(s)
Scientific

Contact name
Dr Martin F Muers

Contact details
Respiratory Unit
Leeds General Infirmaty
Great George Street
Leeds
United Kingdom
LS1 3EX
+44 (0)113 243 2799
none@provided.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00075699

Secondary identifying numbers
E164/44

Study information

Scientific Title
Medical Research Council (MRC)/British Thoracic Society (BTS) phase II feasibility trial of the management of mesothelioma

Acronym
MESO-1

Study objectives
The incidence of mesothelioma is rising rapidly in the UK. There is no generally accepted standard treatment. The British Thoracic Society (BTS) recommends active symptom control (ASC). It is not known whether chemotherapy in addition prolongs survival or provides worthwhile palliation with acceptable toxicity.

The aim of the present study was to assess the acceptability of the trial design to patients and the suitability of two standard quality of life (QL) questionnaires for mesothelioma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multicentre Research Ethics Committees (MREC) approval of the protocol was obtained. Confirmation of Local Research Ethics Committees (LREC) approval was required before a centre could start registering patients

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Mesothelioma

Interventions
Three Arms:
1. Active symptom control (ASC) only
2. ASC and mitomycin (8 mg/m^2), vinblastine (6 mg/m^2) and cisplatin (50 mg/m^2) every 21 days for four cycles
3. ASC and vinorelbine six weekly injections (30 mg/m^2) followed by a two week interval and a further course of six weekly injections

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Mitomycin, vinblastine, cisplatin, vinorelbine

Primary outcome measure
The outcome measures were:
1. The acceptability of the study design to patients
2. Suitability of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) and EORTC Lung Cancer 13-item module (LC13) and Functional Assessment of Cancer Therapy - Lung (FACT-L) QOL questionnaires for mesothelioma
3. Palliation

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/09/2000

Completion date
31/08/2003

Eligibility

Key inclusion criteria
1. Microscopically and immunohistochemically confirmed malignant mesothelioma including epithelial and other histological types
2. Any symptomatic pleural effusion treated and brought under control before trial entry
3. Computed tomography (CT) scan to be performed within a month prior to randomisation
4. Patients who have undergone surgical resection of mesothelioma are eligible provided two CT scans, six weeks apart show stable or progressive disease
5. No previous chemotherapy for mesothelioma
6. No other disease or previous malignancy
7. World Health Organization (WHO) performance status zero to two

8. Medically fit to receive chemotherapy
9. Quality of life (QOL) forms completed
10. Signed informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
120

Total final enrolment
409

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/09/2000

Date of final enrolment
31/08/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Respiratory Unit
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

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

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Feasibility study results:	01/02/2004		Yes	No
Results article	Main trial results:	17/05/2008		Yes	No
Plain English results		28/09/2009	29/10/2021	No	Yes