

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
Registration date 21/09/2000	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/10/2021	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00075699

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre**Respiratory Unit**

Leeds

United Kingdom

LS1 3EX

Sponsor information

Organisation

Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes