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

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

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Contact details

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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