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Malignant mesothelioma - can we improve quality of life?

Submission date	Recruitment status	[X] Prospectively registered
12/12/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/01/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/03/2020	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-improving-quality-life-people-mesothelioma-chest-respect-meso

Study website
http://www.respect-meso.org/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03068117

Secondary identifying numbers
RESPECT-Meso 6.0, 17/02/2015

Study information

Scientific Title
A multicentre non-blinded randomised controlled trial to assess the impact of Regular Early SPEcialist symptom Control Treatment on quality of life in malignant Mesothelioma - 'RESPECT-Meso'

Acronym
RESPECT-Meso

Study objectives
Can early referral to specialist palliative care services in newly diagnosed mesothelioma patients result in improved quality of life for patients and their caregivers?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Hampstead , 26/01/2012, ref: 12/LO/0078

Study design
Multi-centre randomised non-blinded parallel group controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Patient information can be found at http://www.respect-meso.org/patients%20and%20carers.htm

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

Interventions

Regular early Specialist Symptom Control Treatment (SSCT) and Standard Therapy.

In the regular early SSCT group, patients will be seen within three weeks of randomisation by the SPC team (regardless of, and in addition to, all other treatments being offered). The initial meeting will be an approximately 1 hour consultation with a member of the Specialist Palliative Care team. This may be either a Consultant or Specialist Palliative Care Clinical Nurse Specialist (SPCCNS).

Patients will then continue to be seen regularly on at least a 4 weekly basis (regardless of other treatments, interventions and symptoms) by a member of the SPCT, with consultations lasting approximately 30 minutes. These monthly reviews will continue until end of trial (EOT) or patient death.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary objective of this randomised controlled study is to assess the impact of regular early specialist symptom control treatment (SSCT) involvement on global quality of life (QOL) in patients recently diagnosed with malignant pleural mesothelioma (MPM) 12 weeks post randomisation as compared to standard care.

Secondary outcome measures
The secondary objectives are to assess the impact of regular early SSCT involvement in the care of patients recently diagnosed with MPM on the following:
1. QOL in patients after 24 weeks
2. Patient mood at 12 and 24 weeks
3. Primary caregiver QOL and mood at 12 and 24 weeks, and 24 weeks after patient death
4. Overall survival between the two study groups
5. Healthcare utilisation and healthcare costs
6. The cost-effectiveness of regular early SSCT when compared to usual practice

Added 21/08/2014:
7. Sub-group analysis of HRQoL at 12 and 24 weeks for patients based on the neutrophil, lymphocyte ratio and radiological staging at time of diagnosis

Overall study start date
12/01/2014

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Histological or cytological confirmation of malignant pleural mesothelioma (MPM)
2. Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0-1. (Asymptomatic patients score 0; symptomatic but ambulatory patients score 1)

3. The diagnosis of MPM received within the last 6 weeks
4. Ability to provide written informed consent in English and comply with trial procedures
5. Males and females aged 18 and over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
174 patients

Total final enrolment
174

Key exclusion criteria
Current exclusion criteria as of 21/09/2015:
1. Other known malignancy within 5 years (excluding localised squamous cell carcinoma of the skin, cervical intraepithelial neoplasia, grade III and low grade prostate cancer (Gleason score <5, with no metastases)).
2. Significant morbidity which the lead physician (or MDT) feel will unduly confound or influence QOL.
3. Those patients the MDT judge require referral to the SPCT at the point of diagnosis.
4. Concurrent, or less than 3 months, since participation in another non-mesothelioma clinical trial that may affect QOL.
5. Participation in a concurrent mesothelioma trial, within 12 weeks after randomisation, that may affect QOL.
6. Referral at the time of recruitment for cytoreductive, tumour de-bulking, radical decortication or extrapleural pneumonectomy surgery for MPM. (Video Assisted Thoracoscopic Surgery or 'mini' thoracotomy for pleurodesis and diagnosis attempts are permissible.)
7. Chemotherapy treatment for MPM initiated prior to consent.
8. A significant history of depression / anxiety / psychiatric illness requiring specialist hospital care within the last 12 months.

Previous exclusion criteria:
1. Other known malignancy within 5 years (excluding localised squamous cell carcinoma of the skin, cervical intraepithelial neoplasia, grade III and low grade prostate cancer (Gleason score <5, with no metastases).
2. Significant morbidity which the lead physician (or MDT) feel will unduly confound or influence quality of life (QOL).
3. Those patients the MDT judge require referral to the SPCT at the point of diagnosis.
4. Concurrent, or less than 3 months, since participation in another clinical trial that may affect QOL.
5. Referral at the time of recruitment for cytoreductive, tumour de-bulking, radical decortication

or extrapleural pneumonectomy surgery for MPM (Video Assisted Thoracoscopic Surgery or mini thoracotomy for pleurodesis and diagnosis attempts are permissible)
6. Chemotherapy treatment for MPM initiated prior to consent.
7. A significant history of depression / anxiety / psychiatric illness requiring specialist hospital care within the last 12 months.

Date of first enrolment
03/03/2014

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Australia

England

United Kingdom

Wales

Study participating centre
Queen Alexandra Hospital
United Kingdom
PO6 3LY

Study participating centre
Norfolk & Norwich University Hospital
United Kingdom
NR4 7UY

Study participating centre
University Hospital of North Durham & Darlington Hospital
United Kingdom
DH1 5TW

Study participating centre
North Manchester General Hospital
United Kingdom
M8 5RB

Study participating centre
South Tyneside District Hospital
United Kingdom
NE34 0PL

Study participating centre
New Cross Hospital
United Kingdom
WV10 0QP

Study participating centre
Broomfield Hospital
United Kingdom
CM1 7ET

Study participating centre
Southmead Hospital
United Kingdom
BS10 5NB

Study participating centre
Royal Gwent Hospital
United Kingdom
NP20 2UB

Study participating centre
Great Western Hospital
United Kingdom
SN3 6BB

Study participating centre
Musgrove Park Hospital
United Kingdom
TA1 5DA

Study participating centre
Wythenshawe Hospital
United Kingdom
M23 9LT

Study participating centre
Basildon Hospital
United Kingdom
SS16 5NL

Study participating centre
City Hospital & Sandwell Hospital
United Kingdom
B71 4HJ

Study participating centre
Southampton General Hospital
United Kingdom
SO16 6YD

Study participating centre
Sir Charles Gairdner Hospital
Australia
6009

Study participating centre
Royal Hampshire County Hospital
United Kingdom
SO22 5DG

Study participating centre
North Tyneside General Hospital
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NE29 8NH

Sponsor information

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Sponsor type
Hospital/treatment centre

Website
http://www.porthosp.nhs.uk/departments/Research/research-innovation.htm

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Charity

Funder Name
British Lung Foundation (UK) - Asbestos Project Grant Ref.: APG12-13

Alternative Name(s)
BLF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

2015 poster abstract presented at 13th Annual British Thoracic Oncology Group Conference: https://www.lungcancerjournal.info/article/S0169-5002(15)50176-1/abstract

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	19/09/2014		Yes	No
Results article	results	01/04/2019	09/08/2019	Yes	No