

# Malignant mesothelioma - can we improve quality of life?

<b>Submission date</b> 12/12/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 31/01/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/03/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

### Contact name

Prof Anoop Chauhan

### Contact details

Portsmouth Hospitals NHS Trust  
Department of Respiratory Medicine  
Queen Alexandra Hospital  
Southwick Hill road  
Cosham  
Portsmouth  
United Kingdom  
PO6 3LY  
+44 (0)23 9228 6000  
[chief-investigator-ajc@respect-meso.org](mailto:chief-investigator-ajc@respect-meso.org)

## 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**  
United Kingdom  
NE29 8NH

**Sponsor information**

**Organisation**

Portsmouth Hospitals NHS Trust (UK)

**Sponsor details**

c/o Kate Greenwood  
Research and Development Department  
Research Office  
First Floor, Gloucester House  
Queen Alexandra Hospital  
Southwick Hill Road  
Cosham  
Portsmouth  
England  
United Kingdom  
PO6 3LY  
+44 (0)23 9228 6236  
research.office@porthosp.nhs.uk

**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](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?
<a href="#">Plain English results</a>				No	Yes
<a href="#">Protocol article</a>	protocol	19/09/2014		Yes	No
<a href="#">Results article</a>	results	01/04/2019	09/08/2019	Yes	No