MALIGNANT MESOTHELIOMA – CAN WE IMPROVE QUALITY OF LIFE?

Re: Invitation to participate in mesothelioma palliative care trial -

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"

Why do this study?

The UK has the highest prevalence of mesothelioma worldwide and incidence is increasing and predicted to peak in 2015-2025. The UK also has the highest death rate from malignant mesothelioma in the world accounting for 1 in 170 deaths.

This multi-centre randomised controlled trial seeks to examine the effect of **regular early specialist symptom control treatment** on quality of life and mood of patients diagnosed with malignant pleural mesothelioma, their carer's quality of life and mood, patient survival, and cost-effectiveness to the healthcare system.

What are the benefits of participating in this study?

RESPECT-Meso has been peer reviewed by a competitive grant process, and as a high quality study we hope will be of significant benefit to patients and their carer's. This study is on the NIHR portfolio and as such will generate benefits of associated NIHR network support and activity based funding. This study also involves recruiting the patient's primary caregiver as a separate participant giving centres the opportunity to generate double the number of accruals for this RCT. In addition there will be a per patient tariff of £200 at randomisation and £50 on completion of all study paperwork amounting to a total of £250.

What are the main resource implications for participating sites?

The study intervention will be regular early specialist symptom control treatment. Patients in the intervention arm will receive 4 weekly appointments with the specialist palliative care (SPC) team until end of trial or patient death. The study sample size is 174. Based on a recruitment rate of 30% we estimate recruitment of 15 patients per year in a centre seeing approximately 50 mesothelioma patients a year. Each patient in the intervention arm will require 5 hours of SPC time for a follow up period of 9 months. This figure is based on median survival of these patients.

We are hoping to enter our recruitment phase December 2013, and are looking for many sites to participate.

Eligibility criteria

Inclusion criteria

- Histological or cytological confirmation of MPM.
- ECOG PS of 0-1. (Asymptomatic patients score 0; symptomatic but fully ambulatory patients score 1).
- Diagnosis of MPM received within the last 6 weeks.
- Ability to provide written informed consent in English and comply with trial procedures.

Exclusion criteria

- Other known malignancy within 5 years (excluding localised squamous cell carcinoma of the skin, cervical intraepithelial neoplasia, grade III and low grade prostate cancer).
- Significant morbidity which the lead physician (or MDT) feel will unduly confound or influence QOL.
- Those patients the MDT judge require referral to SPC at the point of diagnosis.
- Concurrent, or less than 3 months, since participation in another clinical trial that may affect QOL.
- Referral for cytoreductive, tumour de-bulking, radical decortication or extrapleural pneumonectomy surgery for MPM.
- Chemotherapy treatment for MPM initiated prior to completion of the first questionnaire.
- A significant history of anxiety or depression.

If you are interested in this study and would like further information please contact:

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More information can also be found at: www.respect-meso.org