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MesoTRAP: A feasibility study comparing video-assisted thoracoscopic partial pleurectomy/decortication with indwelling pleural catheter in patients with trapped lung due to malignant pleural mesothelioma designed to address recruitment and randomisation uncertainties and sample size requirements for a phase III trial

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R.C. Rintoul N. Maskell, J.G. Edwards, A.M. Tod, L. Sharples, N. Rahman, A. Coonar, C. Freeman, D. Waller

Introduction:
Trapped lung (TL) in mesothelioma pleural mesothelioma (MPM) is a cause of significant morbidity causing dyspnoea, chest pain and repeated procedures to drain recurrent pleural fluid necessitating multiple hospital visits/in-patient days. We aim to undertake a full phase III randomised controlled trial of video-assisted thoracoscopic partial pleurectomy/decortication (VAT-PD) versus indwelling pleural catheter (IPC) to determine the best method of managing trapped lung in MPM. However, prior to undertaking a full study there are a number of uncertainties that need to be addressed to inform the best design of a phase III study.

i) How prevalent is trapped lung in MPM? ii) Will patients accept randomisation to IPC or VAT-PD? iii) What is the standard deviation of Visual Analogue Scale scores for dyspnoea and chest pain in each treatment group? (Required to estimate parameters that will be included in the sample size estimates for a phase III trial) We will also investigate the feasibility of undertaking a cost-effectiveness analysis from the perspective of the NHS.

Methods:
The primary objective is to determine the ability to randomise 1:1, 36 patients in 18 months into a trial of VAT-PD versus IPC in patients with trapped lung and pleural effusion due to MPM. Data will be collected on: i) The prevalence of trapped lung in patients with MPM ii) Visual Analogue Scale scores for dyspnoea and chest pain and the patterns of change over time in each treatment group iii) Quality of Life at baseline, 1, 3, 6 and 12 months post randomisation iv) Collection and documentation of adverse events and resource use data v) Collection and documentation of Resource Use Data.
A qualitative sub-study (20 randomised patients and 10 who decline) will examine patient experience of the interventions and factors influencing patient decisions to participate and accept randomisation or not.

Results:
No results to date.

Conclusion:
The study which is funded by the NIHR Research for Patient Benefit Scheme opened to recruitment in the UK in July 2017.