Marie Curie Cancer Care Research Programme - Trial Grant

Trial details

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Sonographic and Biological Indicators of Malignant Pleural Effusion Efficacy (SIMPLE) - a randomised trial

Duration of project: 48 months
Start date: 01/03/2014 (TBC)
Budget: £376k (TBC)

Abstract

Background

Malignant pleural effusion (MPE) is a common and increasing problem. Pleurodesis using sterile talc is the standard of care for MPE, and is successful in 70-80%. The procedure requires a catheter to be placed in the chest, full drainage of the chest and subsequent pleurodesis, but there is no robust evidence addressing the time course of pleurodesis occurrence, nor the optimal timing of drain withdrawal. Thoracic ultrasound is increasingly used at the bedside, and pilot data suggest it may be useful in the diagnosis of pleural adhesion soon after talc administration.

Aims

1. Establish if a novel radiological investigation (thoracic ultrasound) can improve quality and efficacy of care for MPE patients undergoing talc pleurodesis.
2. Establish a biobank of prospectively collected biological samples and radiology in patients undergoing talc pleurodesis, linked to robust outcome data, to investigate factors associated with pleurodesis “success” and redefine the current understanding in a patient centred model.

Methods

1. Conduct a randomised multicentre controlled trial of the use of thoracic ultrasound during the first 24-72 hours post talc administration in patients with MPE, to assess if this accurately identifies pleural adherence early in treatment, permitting shorter hospital stay without reducing pleurodesis success.
2. Assess potential health economic impacts of this new treatment paradigm.
3. Collect robust outcomes and sequential biological samples, and statistically model parameters against clinically important outcomes (pleurodesis success, relief of breathlessness, improvement in quality of life) to establish predictors of “clinical success” in talc pleurodesis, to redefine the role of interventions in a patient centred model, and permit individualisation of care.

How the results of this research will be used

If thoracic ultrasound is able to identify patients with a high likelihood of pleurodesis success early after talc administration, this will change the current treatment paradigm for thousands of patients / year. This may permit earlier discharge from hospital and promote improvements in quality of life and substantial healthcare cost reductions. Identification of potential predictors of outcome “success” in talc pleurodesis will revolutionise the use of pleurodesis, with the potential to individualise patient treatment. This will permit rational selection of potentially dangerous interventions, and targeting of these interventions to those who would benefit most. Focus on outcomes important to patients (breathlessness, chest pain, quality of life) and clinicians (hospital stay, healthcare costs) ensures any results are translatable to real patient and healthcare system benefits.