

CareSearch Project	0085
Research Studies Register: Registration Proforma	
Study Title : A prospective, randomised, placebo-controlled, double-blind, cross- over study of the efficacy of sustained-release low dose morphine in the subjective sensation of dyspnoea due to maximally treated primary pulmonary hypertension in opioid naive participants.	
Brief description of the study:	
<p>Background: Dyspnoea is a source of physical and psychological distress. By definition, people with severe primary pulmonary hypertension have breathlessness despite maximal therapy with new therapies for primary pulmonary hypertension. Opioids have been studied for the relief of breathlessness predominantly in people with chronic obstructive pulmonary disease although people with cancer and heart failure have been included.</p> <p>Objective: This study specifically studies people with primary pulmonary hypertension for whom breathlessness is a significant symptomatic problem, to establish whether there is benefit from sustained release morphine, and if so, what magnitude of benefit, and the clinical characteristics of those who are most likely to respond to this intervention.</p> <p>Study design: Each participant will be randomised to one week on arm A or B, one week wash out period and then the arm they did not receive initially. Participant involvement will be for 21 days. The active arm will be a once-daily morning 20mg Kapanol (sustained release morphine) capsule taken orally for 7 consecutive days and 1-2 Coloxyl with Senna tablets (a laxative) taken daily to treat constipation. The control arm will be placebo Kapanol and placebo laxatives.</p> <p>Assessment: Participants will keep a diary for 21 days. Analysis will be based primarily upon the data from days 5, 6, 7 and 19, 20, 21. Participants will be asked to indicate twice daily the intensity of their dyspnoea and other questions to assess their breathlessness over the last 24hrs (each utilising a Visual Analogue Scale (VAS)), their exercise tolerance(using the Medical Research Council of Great Britain Scale for Dyspnoea), the degree of sedation, confusion, nausea, vomiting and constipation (using a categorical response question format in line with the National Cancer Institute Common Toxicity Criteria for Adverse Events), the overall feeling of well being and the quality of sleep (using a modified Borg scale).</p> <p>The primary outcome: is the mean of dyspnoea VAS scores on the last 3 days of each treatment. This will be calculated separately for morning (am) and evening (pm) scores.</p> <p>Sample Size: a previous study (Abernethy et al), which used a similar design in a different patient group, provided sufficient power to detect a treatment effect. That study had 38 evaluable patients and is it hoped we will recruit 40 patients.</p>	
Study Methodology: (Please mark with an x which type of study methodology)	
	Epidemiology
	Health Services / Health Economics / Quality Improvement

	Qualitative, Observational or Descriptive				
	Mixed Method				
	Systematic Review				
X	Intervention: RCT				
	Intervention: Comparative or cohort study				
	Intervention: Case series				
Project details:					
Funding source (Optional):					
Has the study received ethics approval?	X	Yes		No	Not applicable
Project starting date: January 2009					
Project completion date: Until sample size has been achieved					
Multi site:	X	Yes		No	Not applicable
RESEARCHERS					
Principal Investigator (name)	Prof. David Currow				
Contact Details	Department of Palliative and Supportive Services Flinders University, 700 Goodwood Road, DAW PARK SA 5041 Ph: (08) 8275 1732 , Fax: (08) 8374 0350 , Mobile: 0401 710 240 E-mail: david.currow@health.sa.gov.au				
Investigator B (Name)	Dr Dimitar Sajkov				
Investigator C (Name)	A/Prof Christine McDonald				
Investigator D (Name)	Dr. Amy Abernethy				
Investigator E (Name)	Dr Peter Allcroft				
Associated publications / reports: None					
Topics					
<ul style="list-style-type: none"> • Respiratory symptoms and their treatment • Drug trial 					

