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Title: The second therapeutic intervention in malignant effusion trial (TIME2): A randomised controlled trial to assess the efficacy and safety of patient controlled malignant pleural effusion drainage by indwelling pleural catheter compared to chest drain and talc slurry pleurodesis

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Body: Introduction: Malignant pleural effusions (MPEs) can be treated by indwelling pleural catheter (IPC) or chest drain and talc pleurodesis (usual care). This is the first direct, randomised comparison of these techniques as initial therapy assessing patient reported outcomes. Methods: Randomised trial of IPC versus usual care (1:1) in patients with symptomatic MPE. IPCs were inserted as day cases, followed by patient education and home drainage. Usual care was admission for chest drain and talc pleurodesis in patients with good lung re-expansion. The primary outcomes were daily visual analogue scale (VAS) scores of breathlessness and chest pain over 42 days (100mm line, 0mm = no breathlessness/chest pain, 100mm = maximum breathlessness/pain). Results: 106 patients were randomised. Dyspnoea improved in both arms, with no significant difference in intensity (mean VAS: IPC 24.7mm (SD 18.9), usual care 24.4mm (SD 17.0), difference 0.16mm, 95% CI -6.82 to 7.15, p=0.96). Dyspnoea decreased by mean 37mm (SD 27.1) IPC arm and 30.2mm (SD 27.7) usual care arm. Chest pain decreased from baseline in both arms (mean VAS: IPC

20.5mm (SD 18.2), usual care 17.6mm (SD 16.0), difference 5.4mm, 95% CI -3.0 to 13.8, p=0.21). Preliminary analysis demonstrated lower initial hospital stay in the IPC group (median days 0 (IQR 0-1) versus 4 (IQR 2-6)). Discussion: IPC and usual care are comparably effective treatments for the relief of breathlessness in patients with MPE. The pain profile of IPC and usual care is similar over 6 weeks.