# #329; AESOP – A RANDOMISED CONTROLLED CROSSOVER STUDY OF INDWELLING PLEURAL CATHETER DRAINAGE SYSTEMS IN PATIENTS WITH MALIGNANT PLEURAL EFFUSIONS



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Consort diagram

# Background

Indwelling pleural catheters (IPCs) are a wellestablished treatment for recurrent symptomatic malignant pleural effusions.

The commonest IPC drainage system utilizes vacuum drainage bottles which are bulky to store, environmentally unfriendly and can cause pain due to their marked negative pressure.

We wanted to evaluate standard drainage bottles against the new Passio pump drainage system.

# Study design

Single centre, crossover, non-blinded 1:1 randomised controlled trial assessing the safety, efficacy and experience of the Passio pump system. Optional qualitative semi-structured interviews upon trial completion

# **Participants**

Patients with a confirmed recurrent, symptomatic malignant effusion requiring long term, intermittent drainage with an indwelling pleural catheter and expected survival > 1 month.

# Randomisation

Patients were randomised to one of two arms. They had an IPC inserted and drained for 2 weeks using one drainage system and then the valve was changed and they drained using the other system for a further 2 weeks before choosing which one they preferred to carry on using.

#### 41 Assessed for eligibility 19 Excluded 7 Ineligible 2 Survival predicated <1 month 2 Non-malignant effusions/not requiring IPC 1 Outside geographic catchment 1 Lacked capacity for informed consent 1 Other 8 Declined 4 Overwhelmed by cancer diagnosis 2 Desired established care pathway 1 No reason given 3 Not approached 22 Randomised VAS score results 11 Randomised to Arm A 11 Randomised to Arm B 9 Received allocated intervention 11 Received allocated intervention 60 70 With Trapped Lung With Trapped Lung 2 Insufficient fluid for IPC § 60 ≸ 50 50 40 40 30 1 Died 1 Withdrew 30 2 Withdrev 1 Deterioration in health secondary to 20 20 2 Deterioration in health secondary to underlying malignancy underlying malignancy 9 Included in primary analysis 11 Included in primary analysis Without Trapped Lung Without Trapped Lung 60 (AS) D C 60 Results 50 40 Demographics 40 30 22 patients randomized and 20 had enough data to 30 20 include in the primary analysis. Mean age 72.4 (SD 20 14.4) years. 70% male. Tumour; Lung (6), Mesothelioma (5), GI (3), Haematological (2), other Post Pre Post Pre Post Pre Passio Pleurx 9/20 had non-expandable lung (NEL) at trial entry.

# Results

Passio Pump Drainage System

### Adverse events

There were 2 hospital admissions in each group during the 4 week study period – These were not due to disease progression.

There were no cases of pleural infection in either group. 2 cases of skin cellulitis around IPC. There was 1 death due to disease progression.

# Qualitative interviews

8 patients underwent a semi-structured qualitative interview. All had completed both arms of the study. 5 male. They preferred the Pasio device and common themes were; 'less pulling sensation during drainage', 'easier to use', 'looked modern, neat and simple', 'able to control speed easier', 'takes up less room', 'more confident using it'

## Patients final choice

Of the 16 patients completing the study – 15/16 opted to continue drainage via the Pasio device and 1/16 continued with Pleurx.

# Conclusion

The Passio pump drainage system was well tolerated, no differences were found in complication rates, volumes of drainage, VAS pain/breathlessness scores. Most patients preferred the Passio system over Pleurx.





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