Participant Flow

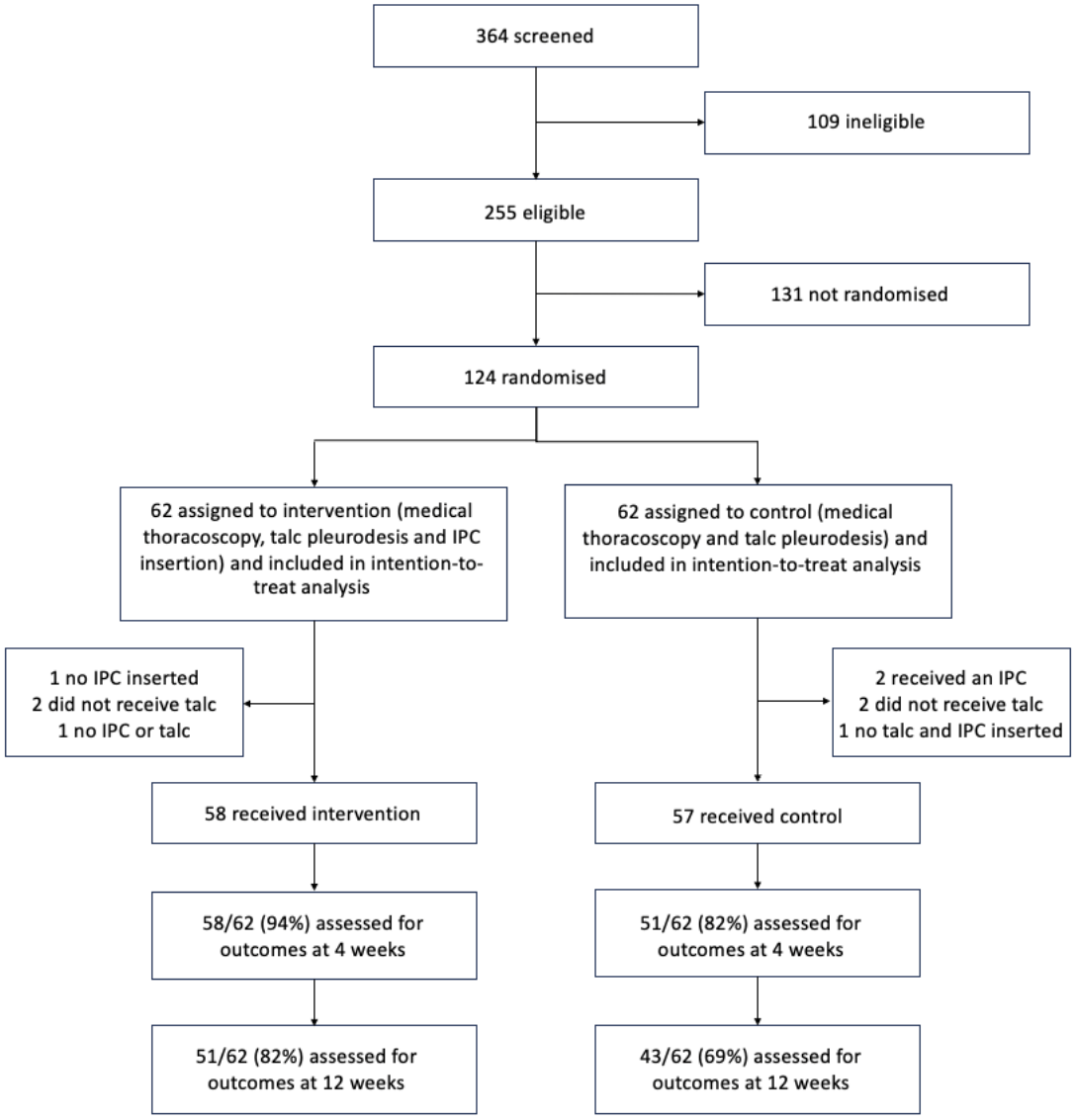

Figure 1

Trial consort diagram

Baseline Characteristics

	Medical thoracoscopy with talc poudrage and IPC insertion **'Intervention'** n = 62 [a]	**Medical thoracoscopy with talc poudrage only** **'Standard care'** n = 62 [a]
Age, mean (SD), years	72.6 (9)	71.4 (10)
Sex		
Female, No. (%)	20 (32)	21 (34)
Male, No (%)	42 (68)	41 (66)
WHO performance status [b], No. (%):		
0	12 (19)	11* (18)
1	36 (58)	40 (66)
2	10 (16)	8 (13)
3	4 (7)	2 (3)
Cancer diagnosis at randomisation (minimisation variables) , No. (%):	8 (13)	8 (13)
Mesothelioma	17 (27)	16 (26)
Cancer other than mesothelioma	37 (60)	38 (61)
Unknown		
Final cancer diagnosis, No (%):		
Lung	19 (31)	16 (26)
Mesothelioma	31 (50)	26 (42)
Breast	3 (5)	10 (16)
Ovarian	0 (0)	1 (1.6)
Lymphoma	1 (1.6)	0 (0)
Upper GI	1 (1.6)	3 (5)
Other	5 (8)	4 (7)
Unknown	2 (3)	2 (3)
Smoking status, No. (%):		
Current	8 (13)	5 (8)
Ex-smoker	32 (52)	33 (53)
Never-smoker	22 (35)	24 (39)
Side of effusion for trial intervention, No. (%):		
Left	28 (45)	31 (50)
Right	34 (55)	31 (50)
Previous pleural intervention (any) on side of trial intervention, No. (%):		
No	10 (16)	16 (26)
Yes	53 (84)	46 (74)
Previous talc pleurodesis on side of trial procedure, No. (%):	0 (0)	1 (1.6)
Current anti-cancer treatment (any), No. (%):		

No Yes	62 (100) 0 (0)	58 (93.5) 4 (6.5)
Current medications, No. (%): Steroids NSAIDs	 3 (5) 2 (3)	 2 (3) 1 (1.6)
Pre-MT VAS dyspnoea, mean (SD), mm	N=60 48.0 (28.7)	N=60 47.6 (31.3)
Pre-MT VAS chest pain, mean (SD), mm	N=60 24.6 (29.7)	N=60 20.6 (28.0)
EORTC QLQ-C30 summary score, mean (SD) EORTC QLQ-C30 global health score, mean (SD)	65.9 (15.7) 43.1 (26.1)	65.6 (17.2) 43.5 (25.9)
EQ5D utility score, mean (SD)	N = 60 0.60 (0.29)	N = 59 0.60 (0.24)

[a] Unless otherwise stated

[b] World Health Organisation performance status scores range from 0 = able to carry out normal activities without restriction; 1 = restricted only on strenuous activity; 2 = restricted on any work activities but capable of all self-care; 3 = symptomatic and in a chair or bed for more than half the day; 4 = confined to chair or bed and unable to carry out any self-care.

*Performance status not recorded in one participant

MT = medical thoracoscopy; IPC = indwelling pleural catheter; SD = standard deviation; WHO = World Health Organisation; VAS = visual analogue scale

Table 1

Baseline characteristics

Outcome measures

Primary Outcome measures

Co-primary outcome data were available for 102 patients for total length of hospital stay (including initial admission for trial procedure and any subsequent readmissions over 4 weeks post procedure). Total length of stay in hospital was a median of 1 day (IQR 1-3) (95% CI 1-2) for patients in the intervention arm and 2 days (IQR 1-3) (95% CI 1-2) for those in the standard care arm (p=0.87), see figure 2. Adjusted analyses showed no difference in total length of stay after controlling for WHO performance status (p=0.33) and cancer type (p=0.95)

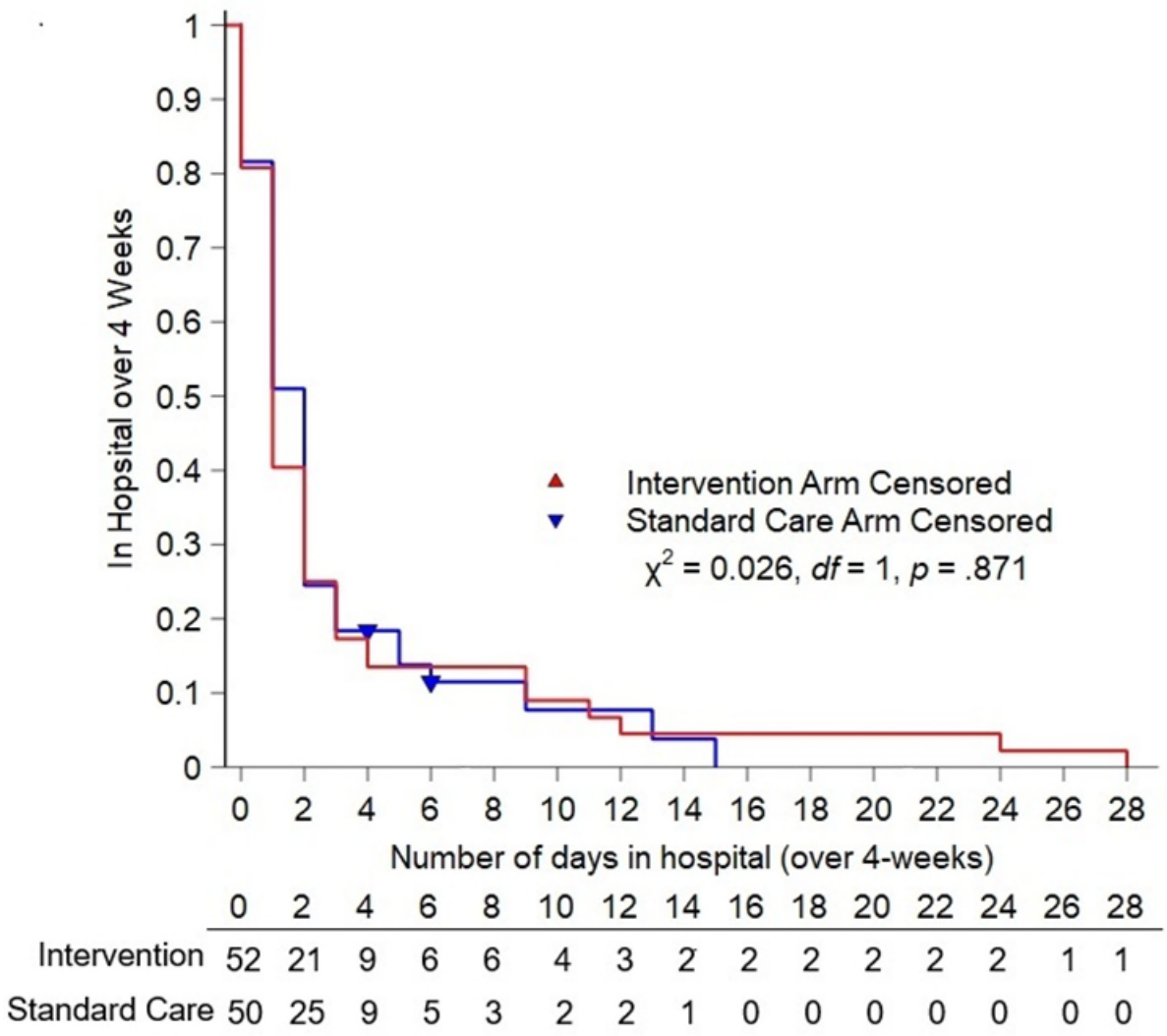

Figure 2
Time in hospital (days) over 4 weeks

Two patients in the IPC group and 2 in the intervention group had no recorded VASd scores and were excluded from the breathlessness co-primary outcome analysis. Mean VASd scores did not differ

between groups over 4 weeks post procedure (intervention arm mean 20.8mm (SD 17.6); n= 57 versus standard care 26.6mm (SD 22.9); n=51; mean difference -5.8 (95% CI -13.5 to 1.9); p=0.14), see figure 3.

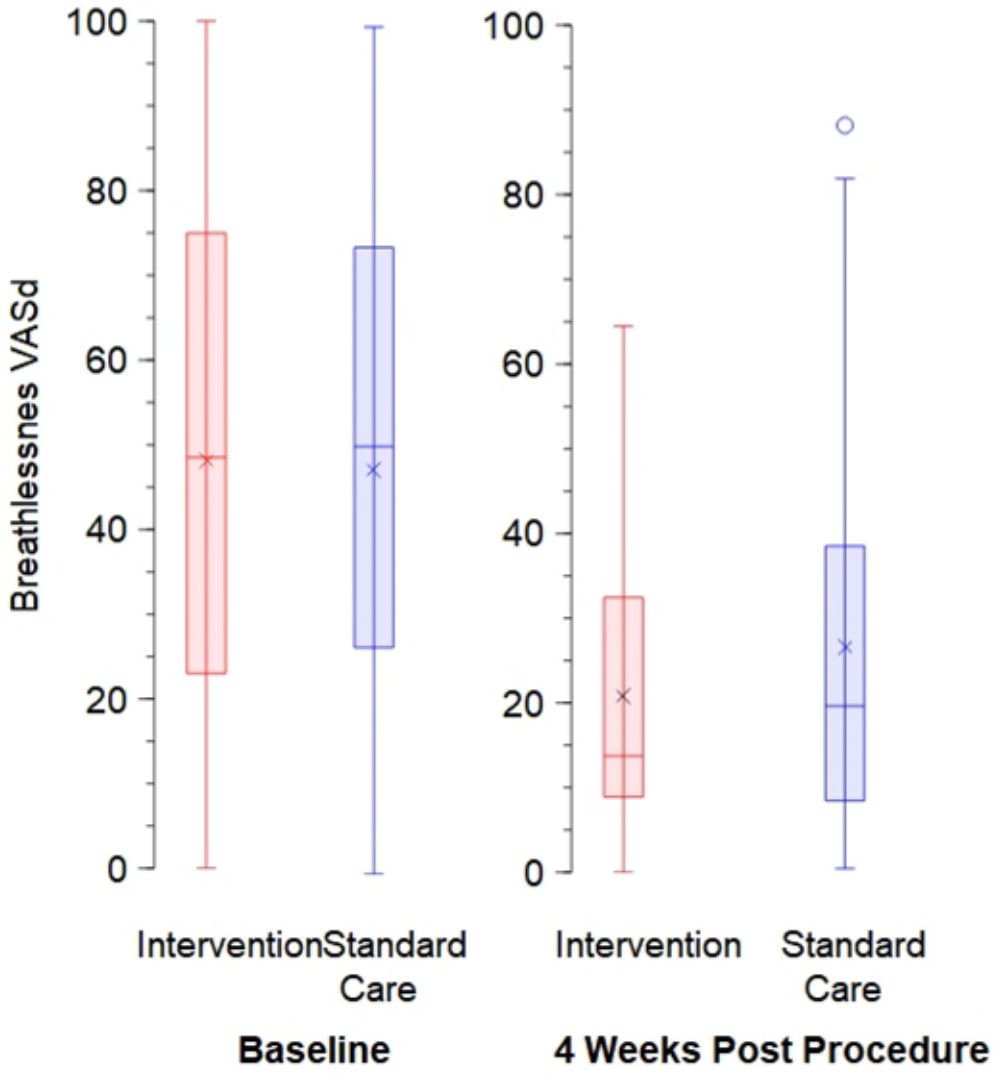

Figure 3
Box plot of VASd scores in intervention arm vs standard care

Adverse events

A total of 94 AE relating to the trial procedure were recorded in the intervention arm and 78 in the standard care arm, see table 2. Three related serious adverse events were recorded, all occurring in the intervention arm. One patient was admitted to hospital for IPC related pain, which improved on removal of the device. Two hospital admissions for management of empyema were recorded in the same patient. No deaths were attributable to trial procedures. There were no statistically significant differences in the number of participants who developed AE rates in the intervention arm versus standard care (61% vs 52%; χ^2 = 1.18, 1df; p=0.28).

Trial intervention related adverse events		
	Medical thoracoscopy with talc poudrage and IPC insertion **'Intervention'** **n = 62**	**Medical thoracoscopy and talc poudrage only** **'Standard care'** **n = 62**
Chest pain requiring analgesia	56 [a]	40
Subcutaneous emphysema	9	13
Hypotension	6	4
Fever	4	3
Post-procedure air leak / pneumothorax	4	9
Pneumonia	1	1
Empyema	2 [b]	1
Subcutaneous infection	3	2
IPC related infection	3	N/A
IPC blockage	1	N/A
Other	5	5
TOTAL	**94**	**78**
[a] One serious adverse event [b] Two serious adverse events, both occurring in the same patient.		

Table 2

Trial intervention related adverse events