ASSERT Study - Basic Results

Participant Flow

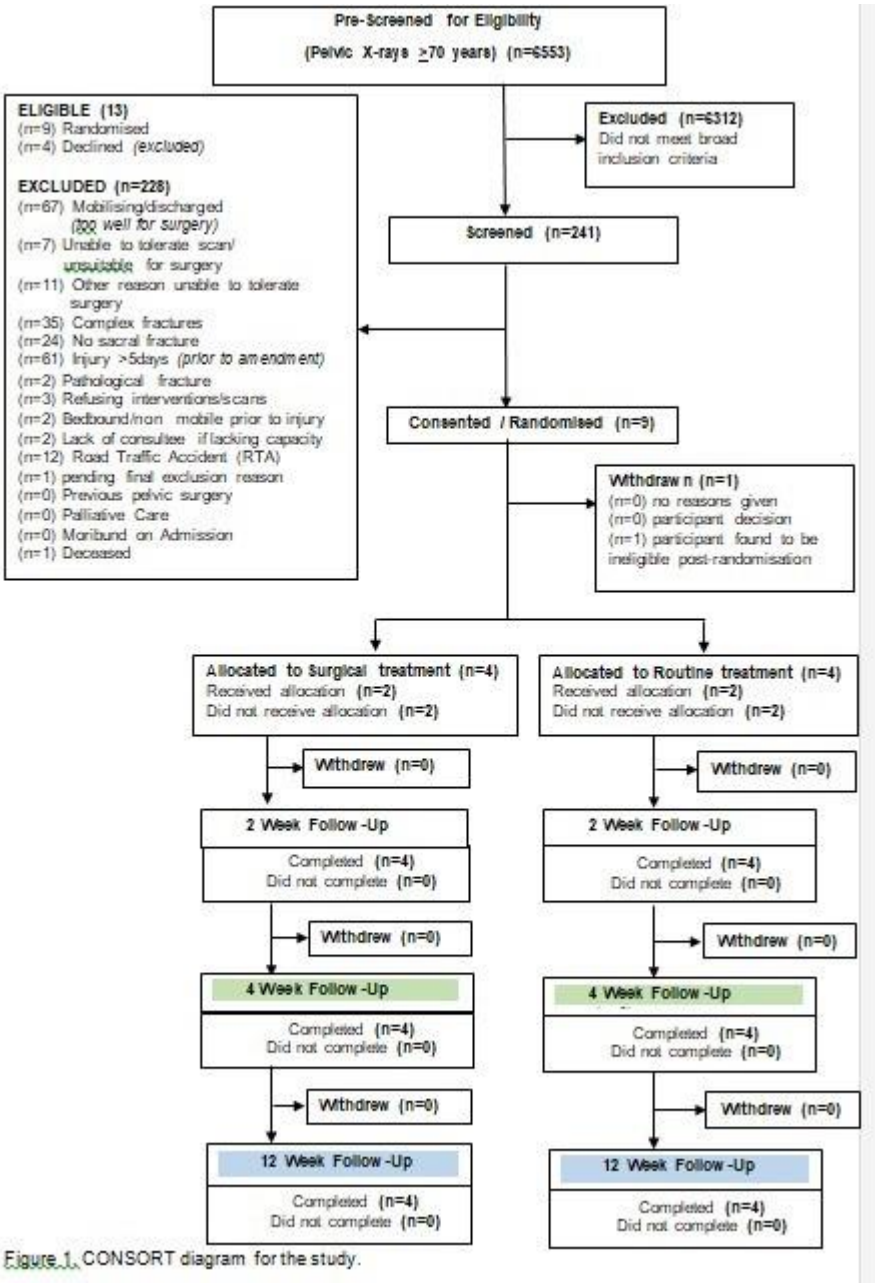

Figure 1. CONSORT diagram for the study.

Baseline characteristics

Characteristics	Surgical treatment group (n=5)*	Non-surgical treatment group (n=4)
Age, median (IQR)[a] years	85 (83, 88)	85.5 (84, 89.5)
Female, n (%)	5 (100%)	4 (100%)
Charlson Co-morbidity Index (CCI), median (IQR)	0 (0, 1)	0.5 (0, 1)
Montreal Cognitive Assessment (MoCA), median (IQR)	23 (16, 23)	24 (22, 29)
Clinical Frailty Scale (CFS), median (IQR)	6 (4, 6)	3 (2.5, 5)
Prescribed strong opioids, n(%)	5 (100%)	4 (100%)
Concomitant acute medical issues, n (%)	4 (80%)	2 (50%)
Presence of delirium, n (%)	0 (0%)	1 (25%)

[a] Inter-quartile range

* 5 patients but 1 withdrawn at the time of surgery (complex fracture)

A total of 4 participants randomised into the study received surgical treatment regardless of their treatment allocation. The overall median time to operation was 6 days. All participants had a combination of cement augmentation and screw fixation. Intra-operatively, one participant reported cement leakage and another one developed a respiratory problem, in addition to also reporting cement leakage and medical complications.

Outcome Measures

Characteristics:	Surgical treatment group (n=4)				Non-surgical treatment gr	
Median (IQR)[a]	Baseline	Week 2	Week 4	Week 12	Baseline	Week 2
Time up and go (TUG), measured in seconds	-	47.2 (29.9, 88.6)	-	22.6 (16.7, 25.1)	-	53.7 (28.0 210.0)*
Roland Morris Disability Questionnaire (RMDQ)	-	13 (11.0, 15.5)	14.5 (9.5, 15.5)	8.5 (4.5, 10.5)	-	17.0 (14.0 22.0)*
Functional Independence Measure (FIM)	77.5 (67.5, 88.0)	114 (91, 119)*	-	120.5 (114.5, 125.0)	77.0 (51.5, 92.5)	100 (57,
Barthel Activities of Daily Living	11 (9, 13)	15.0 (11.5, 18.0)	19 (16, 19)*	19.0 (18.5, 19.5)	9 (5.5, 14.0)	14.0 (7.0
Numeric pain rating scale		10 (9, 10) 4.5 (2.5, 6.0)		5 (4.0, 7.0)* 10 (8, 10)*		5.0 (3.5, 6.5) 7 (6.0, 8.

*Data from 3 participants †Data from 2 participants [a] Inter-quartile range

Adverse Events

12 weeks:

There were 6 SAE which resulted in hospitalisation up to the 12 week follow up period.

5 SAE were in the surgical intervention group on which 3 were in the same patient and 1 in in the non-surgical treatment group.

None of the SAEs in the surgical treatment group were related to the study.

52 weeks:

All patients were still alive at 52 weeks.

There were a further 7 hospitalisations up to the 52 week period, 3 in the surgical arm and 4 in the non-surgical arm. None of these were related to the study.