TRIAL SUMMARY

Trial Title	Randomised controlled trial of the clinical and cost-effectiveness of cervical spine immobilisation following blunt trauma (SIS trial)	
Internal ref. number (or short title)	SIS trial	
Trial Design	A multi-centre, open-label, pragmatic, pre-hospital, non-inferiority randomised controlled trial with health economic evaluation to determine the effectiveness of immobilisation regimes involving movement minimisation and triple immobilisation (current NHS practice) in patients with cervical spine (c-spine) injury recruited in a pre-hospital setting.	
Trial Participants	Patients (any age) in a pre-hospital setting with potential or suspected c-spine injury.	
Planned sample size	2010 participants	
Treatment Duration	The interventions will be administered at initial pre-hospital clinical assessment and will remain in place for as long as is clinically required.	
Follow-up Duration	Participants will be followed-up for 180 days	
Planned Trial Period	01 November 2022 – 31 October 2025 with an internal pilot phase 01 November 2022 – 31 Aug 2024	
	Objectives	**Outcome Measures**
Primary	To determine whether movement minimisation is deemed non-inferior compared to triple immobilisation in relation to functional outcome at hospital discharge.	Functional Independence Measure (Motor) score
Secondary	To determine the effects of immobilisation techniques on clinical, patient-centred and economic outcomes pre-hospital, in hospital and at 180 days post-randomisation.	Need for pre-hospital analgesia Neurological change (randomisation to hospital discharge) Mortality (30, 90 and 180 days) Length of stay in critical care and hospital Further intervention for c-spine injury Costs and resource utilisation Adverse events
Quality of Life	To determine the effects of immobilisation techniques on patient-centred outcomes pre-hospital, in hospital and at 180 days post-randomisation.	Quality of life measurements (EQ-5D-5L/EQ-5D-Y)