Hospital screening interview for the ATLS vs standard care trial

This is the screening interview form for the Advanced Trauma Life Support® vs Standard Care trial planned by Karolinska Institutet along with The George Institute. You have expressed preliminary interest inparticipating in this trial. We are undertaking this hospital screening interview inorder to assess whether the study could be conducted at your hospital. We appreciate your efforts to answer as many of these questions as possible and we will follow up on your responses and any questions you may have in a separate call. Thank you!

Synopsis Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial Rationale Trauma is a massive global health issue. Many training programmes have been developed to help physicians in the initial management of trauma patients. Among these programmes, Advanced Trauma Life Support® (ATLS®) is the most popular, having trained over one million physicians worldwide. Despite its widespread use, there are no controlled trials showing that ATLS® improves patient outcomes. Multiple systematic reviews emphasise the need for such trials.

Aim To compare the effects of ATLS® training with standard care on outcomes in adult trauma patients.

Primary Outcome All-cause mortality within 30 days of arrival at the emergency department.

Trial Design Batched stepped-wedge cluster randomised trial in India.

Trial Population Adult trauma patients presenting to the emergency department of a participating hospital.

Sample Size 30 clusters and 4320 patients.

Eligibility Criteria

Hospitals are secondary or tertiary hospitals in India that admit or refer/transfer for admission at least 400 patients with trauma per year.

Clusters are one or more units of physicians providing initial trauma care in the emergency department of tertiary hospitals in India.

Patients participants are adult trauma patients who presents to the emergency department of participating hospitals and are admitted or transferred for admission.

Intervention The intervention will be ATLS® training, a proprietary 2.5 day course teaching a standardised approach to trauma patient care using the concepts of a primary and secondary survey. Physicians will be trained in an accredited ATLS® training facility in India.

Ethical Considerations We will use an opt-out consent approach, in which consent is presumed unless actively declined. Note that consent here refers to consent to data collection, as it will not be possible for patients to opt out from being subjected to the intervention. This approach is justified because the trial can be considered to involve only minimal risk and the data

22/02/2024 05:51 projectredcap.org TEDCAP