

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2025/018

Scientific title of trial: AEFIX Trial: A Multicentre Randomized Controlled Assessing Safety and Efficacy of a Novel, Affordable Fracture External Fixation System.

Date of commencement (enrolment of first participant):

Progression: 6 months ☐ 1 year ☒ 2 years ☐ 3 years ☐
At completion ☐

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: No

Any changes to trial outcomes after commencement: No

2. Current status

~~Recruitment status: pending/ recruiting/ recruitment complete/ follow-up continuing/ recruitment complete/ follow-up complete/ recruitment suspended / recruitment terminated~~

Number assessed for eligibility: 100

Number recruited and allocated/randomized: 65 (currently recruited)

Number allocated/randomized to each intervention/arm (please edit as relevant):

Arm 1: AEFIX Fixation – 50 (currently recruited – 33)

Arm 2: Control/AO Fixator-50 (currently recruited – 32)

Losses/exclusions after allocation/randomization (please edit as relevant):

Arm 1: No

Arm 2: No

3. Trial output

Date of trial completion ("last patient, last visit"): recruitment is going on trial may end up on September 2026.

Final sample size: recruitment on process.

Summary of Interim/Final data (if available):

In the ongoing analysis of the AEFIX multicenter randomized clinical trial, data from 65 recruited patients show balanced allocation between the AEFIX and AO external fixator groups, with a predominance of young to middle-aged male patients, largely injured due to road traffic accidents. Preliminary blinded primary outcome assessment using anonymized X-rays demonstrates satisfactory fracture reduction and stabilization in both groups, with AEFIX showing comparable performance. Functional recovery analysis using FIX-IT scores and health-related quality of life assessment with EQ-5D indicate progressive improvement from inpatient status to 6 months, with consistently higher mean scores observed in the AEFIX group across follow-up time points. Patient-reported health today scores also demonstrate steady recovery over time, while pocket cost analysis highlights ongoing out-of-pocket expenses related to food and travel, emphasizing the socioeconomic burden of trauma care. Overall, the interim data support the safety, clinical effectiveness, and practical usability of the AEFIX system, justifying continued recruitment, rigorous follow-up, and planned final analysis prior to international dissemination, including presentation at **SICOT** and publication in the **Journal of Public Health and Emergency**.

Abstract presentations of results at scientific meetings

Note: please include a URL link or scanned copy of the abstract

Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
Management of open fractures in Sri Lanka using AEFIX: A frugal Innovation approach to improve trauma care equity.	1.Prof.Rajendra Surenthirakumaran, MBBS, MSc, PGD, MD, Faculty of Medicine, University of Jaffna, 2.Lie Tijauw Tjoen Denny, MBBS, FRCS (Edin), FAMS, Department of Orthopaedic Surgery, Singapore General Hospital, Singapore; SingHealth Duke-NUS Musculoskeletal Sciences Academic Clinical Programme, Duke-NUS Medical School, Singapore, 3.Kiran Jay Agarwal-Harding, MD, MPH Harvard Global Orthopaedics Collaborative, Boston, Massachusetts; Carl J. Shapiro Department of Orthopaedics, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts , 4.Kizher Shajahan Mohamed Buhary, MD, BE, MRCSEd, MMed, FRCSEd, Department of Orthopaedic Surgery, Singapore General Hospital, Singapore; SingHealth Duke-NUS Musculoskeletal Sciences Academic Clinical Programme, Duke-NUS Medical School, Singapore , 5.Alexis Thayaparan Christine Thevamirtha, BSc, Faculty of Medicine, University of Jaffna , 6.Paskaran Pirasanth, BBA, Faculty of Medicine, University of Jaffna, 7.Ajeetha Jeevarajan, B.Pharm, MSc, Faculty of

	Medicine, University of Jaffna , 8.Sinnathurai Majooran, MBBS, MD, District General Hospital, Vavuniya, Sri Lanka , 9.Paramalingam Srigrishna, MBBS, MD (Surg), MRCS (Eng), Teaching Hospital, Jaffna, Sri Lanka 10.Sivananthan Sashikaran, MBBS, MD, MRCS(Eng.), ChM(Edin), Teaching Hospital, Jaffna, Sri Lanka, 11.Thayasivam Gobyschinger, MBBS,MRCS(Edin),MS, Teaching Hospital, Jaffna, Sri Lanka , 12.Muhammad Daniel Azlan bin Mahadzir, PhD, SingHealth Duke-NUS Global Health Institute, 13.Jonas Karlström, MBBS, MSc, SingHealth Duke-NUS Global Health Institute, 14.Sreekanthan Gobishangar, MBBS, MD, MRCS(Eng), MRCS(Edin),Faculty of Medicine, University of Jaffna. Date: 30th October 2025 Title of Conference: APRU Global Health Conference 2025 towards Planetary Health Equity:A Global Call for shared location. Place of presentation: KPPI Gallery (Basement). Basement Level, KPPI Building, University of Malaya, Kuala Lumpur,50603. Page No of Abstract: Abstract ID No – 213 Poster presentation.
	Scanned copy of Abstract attached.

Publications

Note: please include a URL link or scanned copy of the publication

Title of paper	Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)



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Name and signature of Responsible Registrant/
Principal Investigator

Date: 01/05/2026.