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Digital trauma handover

Submission date
19/05/2025

Recruitment status
No longer recruiting

Registration date
20/05/2025

Overall study status
Completed

Last Edited
16/07/2025

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Time is critical in trauma care. Delays, even minutes, can significantly affect outcomes, especially in patients with life-threatening bleeding. This study tests a real-time digital handover system to improve how trauma teams receive patient information from London's Air Ambulance, aiming to reduce delays in treatment for seriously injured patients. The system helps transmit key patient information (injury details, vital signs, treatments) directly from the ambulance team to the hospital before the patient arrives.

Who can participate?
Trauma clinicians (doctors, registrars, paramedics) and trauma patients aged 16 years and over

What does the study involve?
Clinicians complete a risk perception questionnaire after each trauma case, fill out a usability questionnaire every 2 months and take part in interviews to give feedback on system use and impact. There is no direct patient intervention - only data from standard care used with consent.

What are the possible benefits and risks of participating?
The findings will inform the development of a clinical decision support system using AI and lead to future trials focused on improving trauma care efficiency and outcomes. Patient and clinician data will be anonymised and securely stored. There are no changes to current patient care or treatment.

Where is the study run from?
Queen Mary University London (UK)

When is the study starting and how long is it expected to run for?
February 2025 to November 2025

Who is funding the study?
1. Rosetrees Trust (UK)
2. ZOLL Medical Corporation

Who is the main contact?
Dr Zane Perkins, z.perkins@qmul.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Zane Perkins

Contact details
Centre for Trauma Sciences
Blizard Institute
Queen Mary University of London
4 Newark Street
London
United Kingdom
E1 2AT
+44 (0)2073777000
z.perkins@qmul.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
339900

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
EDGE 173654, CPMS 66642

Study information

Scientific Title
Digital decision support to reduce time to treatment in trauma

Study objectives
1. To implement and evaluate a real-time digital handover system, to streamline the transition of care from the pre-hospital setting to the major trauma centre (secondary care).
2. To assess the accuracy of experienced clinicians in evaluating significant risks in trauma patients.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 24/02/2025, Health and Social Care Research Ethics Committee B (HSC REC B) (Office for Research Ethics Committees Northern Ireland (ORECNI), Lissue Industrial estate West, 5 Rathdown Walk, Lisburn, BT28 2RF, United Kingdom; +44 (0)28 95361400; info.orecni@hscni.net), ref: 25/NI/0019

Study design
Prospective observational mixed-methods study

Primary study design
Observational

Study type(s)
Other, Safety, Efficacy

Health condition(s) or problem(s) studied
Traumatic injury

Interventions
The study comprises a mixed methodology approach with five components:
1. Clinical risk perception questionnaire
2. Clinician usability questionnaire
3. Semi-structured clinician interview
4. Quantitative evaluation
5. Hazard analysis

Clinicians complete a risk perception questionnaire after each trauma case, fill out a usability questionnaire every 2 months and take part in interviews to give feedback on system use and impact. There is no direct patient intervention - only data from standard care used with consent.

Intervention Type
Other

Primary outcome(s)
1. Usability measured by the System Usability Scale score and the PAAS Mental Effort Scale at each trauma team activation
2. Perceived usefulness and acceptability based on a semi-structured interview at 2-monthly intervals (beginning, middle, and end of study)

Key secondary outcome(s))
1. Clinician risk perception: clinicians' estimates of patient risks will be measured using a 0-100% probability scale immediately post-resuscitation
2. Clinician risk perception performance: clinician risk estimates will be compared to documented (true) patient outcomes to assess accuracy
3. The patient risks and outcomes that will be measured are:
3.1. In-hospital mortality
3.2. Trauma-induced coagulopathy (TIC), defined as an admission Prothrombin Time ratio (PTr) >1.2
3.3. Significant haemorrhage (≥4 units of blood transfused within 4 hours post-injury)
The patient outcome data used for comparisons are standard clinical indicators routinely collected during trauma care. This study will not involve any additional data collection directly

from patients. Instead, it will utilise retrospective data analysis of existing clinical records to determine the accuracy of clinicians' risk assessments.

Completion date
30/11/2025

Eligibility

Key inclusion criteria
1. Trauma clinicians:
Consultant, Specialist Registrar (resident), or paramedics who have direct involvement in initial assessment, management of adult trauma patients transported by London's Air Ambulance to the Royal London Hospital.

2. Trauma patients:
Aged 16 years or over with traumatic injury

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Key exclusion criteria
Trauma clinicians:
1. Consent: clincians who decline to consent or participate
2. Involvement: clinicians not involved in the initial care of adult trauma patients

Trauma patients:
1. Aged under 16 years
2. Presenting with injuries: burns, hangings, drownings, or acute psychotic episodes without physical injuries

Date of first enrolment
01/05/2025

Date of final enrolment
31/07/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Barts and the London NHS Trust
Alexandra House
The Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Rosetrees Trust

Alternative Name(s)
Teresa Rosenbaum Golden Charitable Trust, Rosetrees

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
ZOLL Medical Corporation

Alternative Name(s)
ZOLL, Zoll Medical Corp., ZOLL Medical, ZMC

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
All data from clinician participants within the study will be fully anonymised. Routine clinical outcome data will be retrospectively captured from Bart's Health NHS trust electronic healthcare records. Patient-level data will be pseudo-anonymised and assigned an identifier case record number prior to full anonymisation.

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository - Barts Cancer Centre Information Technology infrastructure - Safe Haven.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes