ISRCTN41280918 https://doi.org/10.1186/ISRCTN41280918

A study to evaluate whether photographs improve bystanders' ability to find safe injection sites in emergencies

Submission date
17/07/2025

Recruitment status
No longer recruiting

Registration date
08/08/2025

Overall study status
Completed

Last Edited
15/12/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Heavy bleeding is one of the leading causes of preventable death after a serious road accident. Tranexamic acid (TXA) is a medicine that can help stop this type of bleeding, especially if given within the first few hours after injury. Normally it is given by paramedics or doctors, but in the future it might be possible for members of the public (bystanders) to give an injection before emergency services arrive. This study aims to find out whether photographs can help bystanders find the correct place on the body to give an injection of TXA.

Who can participate?
Adults aged 18 or over who do not have a formal medical or nursing qualification. People with basic first aid training were allowed to take part.

What does the study involve?
Each person was given instructions (either just spoken, or spoken plus a photograph) and asked to place a sticker where they thought the injection should go on a simulated casualty sitting in a car. No real injections were given. The position was then assessed by experienced clinicians using photographs. Participants also completed a short questionnaire.

What are the possible benefits and risks of participating?
Although there was no direct benefit to participants, the findings will help emergency services understand how best to support members of the public in an emergency. There were no medical procedures or risks involved in the study. It was a low-risk simulation, and participants were not asked to do anything beyond placing a sticker.

Where is the study run from?
The study was run by researchers from IMPACT – The Centre for Post-Collision Research, Innovation and Translation – in partnership with the Devon Air Ambulance.

When is the study starting and how long is it expected to run for?
The study took place on a single day: 22 November 2024. All data collection was completed on the same day.

Who is funding the study?
The study was funded by The Road Safety Trust and Vision Zero South West.

Who is the main contact for the study?
Prof Tim Nutbeam, timnutbeam@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Tim Nutbeam

Contact details
5 Sandpiper Court, Harrington Lane
Exeter
United Kingdom
EX4 8NS
+44 (0)7779231813
timnutbeam@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A randomised controlled trial of verbal guidance versus verbal guidance supplemented by a photographic aid for bystander identification of intramuscular tranexamic acid injection sites in a simulated road injury scenario

Acronym
BYSTANDERTXA

Study objectives

To determine whether supplementing verbal guidance with a photographic aid improves lay bystanders' ability to accurately identify a safe intramuscular injection site (deltoid region) for tranexamic acid administration in a simulated emergency scenario.

Ethics approval required
Ethics approval not required

Ethics approval(s)
This study involved a simulation-based design with no clinical interventions, administration of medication, collection of personal health data, or biological samples. Participants were only asked to identify a simulated intramuscular injection site on a mannequin or actor.

The UK Health Research Authority's "Is this Research?" decision tool (www.hra-decisiontools.org.uk), aligned with the UK Policy Framework for Health and Social Care Research (2017), confirmed that this activity is not classified as research requiring NHS Research Ethics Committee (REC) approval. The activity was therefore conducted as a service evaluation and public engagement exercise, meaning formal REC review was not required.

All participants provided written informed consent, were advised of their right to withdraw at any time, and no participants were under 18.

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Trauma-related haemorrhage (simulated context)

Interventions
Participants were randomised (1:1 block randomisation) into two groups:
• Control (Verbal guidance): Participants received remote verbal instructions to identify the deltoid IM injection site on a simulated injured person.
• Intervention (Verbal + photographic aid): Participants received the same verbal instructions supplemented with a photographic aid to assist in identifying the injection site.

Each participant located the site and placed a sticker to mark it. Standardised photographs were taken, and three independent clinicians reviewed these to assess safety. Total participation time: approximately 15 minutes.

The primary data capture occurred during the simulation session, where participants immediately marked their chosen intramuscular injection site using an adhesive visual marker. The marker placement was recorded through standardised photographs at the time of participation. Final determination of the primary outcome and some secondary outcomes was subsequently performed post hoc by a panel of expert raters who independently reviewed the anonymised photographs within 30 days of data collection.

Intervention Type
Behavioural

Primary outcome(s)
Proportion of participants who correctly identified a safe intramuscular injection site, defined as majority agreement (≥2 of 3 raters) from independent clinical experts reviewing the standardised photographs post hoc (up to 30 days following data collection)

Key secondary outcome(s))
1. Rater concern about injection site safety: Proportion of sites eliciting concern, as assessed by independent clinical experts during post hoc photograph review (up to 30 days following data collection).
2. Participant confidence: Self-reported confidence in delivering an intramuscular injection, measured using a structured questionnaire immediately post-task
3. Effect of participant demographics and prior training: Association between participant age, sex, and prior first aid or injection training (collected via baseline questionnaire) and the accuracy of injection site identification, as determined by expert post hoc photograph review.

Completion date
22/11/2024

Eligibility

Key inclusion criteria
1. Aged 18 years and older
2. Able to give informed consent
3. No formal medical or nursing qualifications

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
64

Key exclusion criteria

1. Aged under 18 years
2. Formal qualification in medicine, nursing, or paramedicine

Date of first enrolment
22/11/2024

Date of final enrolment
22/11/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Exeter
Stocker Road
Exeter
England
EX4 4PY

Sponsor information

Organisation
Devon Air Ambulance

Funder(s)

Funder type
Charity

Funder Name
Road Safety Trust

Funder Name
Vision Zero South West

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated and/or analysed during the current study will be available upon request from Tim Nutbeam, timnutbeam@nhs.net.

Type of data: Anonymised participant-level data (demographics, site markings, expert ratings).
Timing: Available from the corresponding author upon reasonable request following publication of the main results.
Consent: Participants provided written informed consent for anonymised data use.
Anonymisation: All identifiers removed; only study ID numbers retained.
Restrictions: No legal or ethical restrictions apply.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2025	15/12/2025	Yes	No