DISCLOSE

SOP 1

Version 1

Date: 02/09/2025

Screening and recruitment - DISCLOSE TRIAL

This standard operating procedure (SOP) outlines the procedures for including and randomizing participants in the trial titled:

A Randomised Controlled Trial Comparing No Reduction to Closed Reduction for Distal Radius Fractures in Patients 65 Years and Older (DISCLOSE trial)

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Initial Workflow in the ED

1. **Conduct standard clinical and radiographic evaluation** of the wrist.
2. **Assess eligibility** according to the protocol criteria.
3. **Provide verbal and written information** about the trial to eligible patients.
4. **Fill REDCap + randomize**
5. **Treat the patient according to the allocation**

Eligibility Screening

Inclusion criteria
- Age 65 years or older - Independent living patients - Displaced distal radius fracture (AO/OTA 23A/23C) with 15–40 degree dorsal angulation; and/or shortening of the radius by more than 2 mm. Associated ulnar styloid fracture is permitted - Low energy injury (fall from ≤1 m)

Exclusion criteria
- Patient unable to provide consent - Patients who are actively working in a paid position - Volar angulation, partial articular fractures (AO/OTA 23B) - Concomitant fracture of the ulna proximal to the base of the styloid process - Associated fracture or dislocation in any other body part that would affect the use of the injured distal radius - Distal radius fractures in both arms - Open injury, Gustilo 2 or higher - No bony contact between the main fragments - High energy injuries

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Verbal and written information

Verbal information examples

"This study compares two common treatments for wrist fractures - both are used regularly in hospitals, and we're trying to find out if they are equivalent"

"You will receive the same high level of care as always, no matter which group you're in."

“By joining the study, you will have regular check-ins and easier access to study staff if any concerns arise.”

"Your participation helps improve future treatment for older adults with similar fractures, you will be contributing to better evidence for care decisions."

Written information

1) **Participant Information Sheet**
2) **Informed Consent Form**

Encourage the patient to read the form thoroughly and ask any questions they may have.

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REDCap & Randomisation

- Obtain **written informed consent** before any trial procedures.
- **Randomisation must occur immediately** in the emergency room using the REDCap online randomisation system.
- Allocation is **1:1** to either:
    - **No Reduction + Casting**
    - **Closed Reduction + Casting**

Intervention per Allocation

No Reduction Group:

- Apply a **dorsal cast** after the initial radiograph.
- Take **control radiograph** after casting.
- Advise **active finger movement** and **light hand use** immediately.
- Cast to be removed after **5 weeks** per local protocol.
- Provide the **standardised exercise protocol**.
- **No further radiographs** until the 3-month follow-up.

Closed Reduction Group:

- Perform **closed reduction under local anaesthetic** (lidocaine infiltrated at fracture site).
- Take **post-reduction radiographs** (for assessment only, does not influence care).
- Apply cast and follow the **same post-casting pathway** as the no-reduction group.

Please use the **standardized paragraph** in the medical records:

The patient has been enrolled in the DISCLOSE trial (ETL R25001), a multi-centre RCT comparing no reduction vs. closed reduction for displaced distal radius fractures in patients aged ≥65. The cast will be removed at 5 weeks according to local protocol; however, routine radiographs will not be taken at that time.

The patient will receive a follow-up phone call from the study nurse in the coming days and will be scheduled for follow-up visits at 3 and 12 months. All follow-ups will be coordinated by the research team.

The patient has been given contact information for the study nurse and advised to report any complications (e.g., carpal tunnel symptoms) without delay.

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Observational Arm (if patient declines randomisation)

- Offer participation in the **observational cohort**.
- Proceed with **standard care** (closed reduction + casting).
- Obtain **consent form for follow-up** using the same procedures.
- Fill the REDCap ”**DISCLOSE - Observational arm**”

Screening log

- If the patient declines participation in both the trial and the observational arm, they should still be added (without identifiable information) to the REDCap database under **”DISCLOSE – Decliners”.**

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After Recruitment

- **Baseline data** will be collected by study personnel via phone within 2 working days.
- Send the consent form to the study nurse according to your guideline.

Important Notes for Recruiters

- **Do not disclose treatment allocation** to outcome assessors (study nurse or other blinded personnel).
- All randomisation and data entry must be done via the **REDCap system**.
- Maintain **strict confidentiality** and comply with **Good Clinical Practice (GCP)** and local ethical guidelines.