WARWICK
CLINICAL TRIALS UNIT

PARAMEDIC 3

Medication Route in Cardiac Arrest

Paramedic trial training

PARAMEDIC-3: Pre-hospitAl RAndomised trial of MEDICation route in out-of-hospital cardiac arrest

How to enrol patients in the trial

The sequence below shows the process for enrolling patients in the trial

Attend cardiac arrest and establish need for vascular access

Assess patient for eligibility

Perform randomisation

Deliver intervention as per randomisation

Assess patient for eligibility

To be eligible for PARAMEDIC-3, the patient must meet BOTH of the inclusion and have none of the exclusion criteria

Inclusion criteria

✓ Out-of-hospital cardiac arrest receiving cardiopulmonary resuscitation. Patients must be in cardiac arrest and require cardiac arrest drugs.

✓ Requirement for vascular access to administer cardiac arrest drugs

Exclusion criteria

✗ Children (known, look or appear to be under 18 years).

✗ Pregnancy (known, look or apparent)

✗ Already have vascular access, intravenous or interosseous

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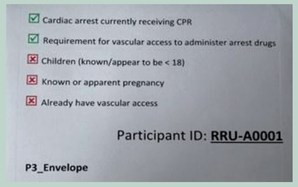
Randomisation

- Envelopes will be allocated once trial training is complete
- Only one envelope should be collected and retained by the trial paramedic
- Each envelope must be logged by emailing the randomisation number and your name to PARAMEDIC3@swast.nhs.uk or text/WhatsApp to 07771956183.
- Envelopes must be kept safely, please report lost/damaged
- One envelope should be opened at the cardiac arrest once the patient is confirmed as eligible for the trial
- The first on scene trial trained paramedic should open their allocated envelope and enrol the patient.
- Qualified paramedics may perform the intervention even if they are not trial trained.
- Envelopes must not be left on scene at the end of the cardiac arrest event. Contents should be disposed of in the clinical waste.

Perform randomisation

Randomisation is the process by which participants are allocated by chance to one of the treatments, either IV or IO. PARAMEDIC-3 uses a system of opaque envelopes for the randomisation system.

Front of envelope



Inside envelope

IV
(Intravenous route)
Participant ID: **RRU-A0001**

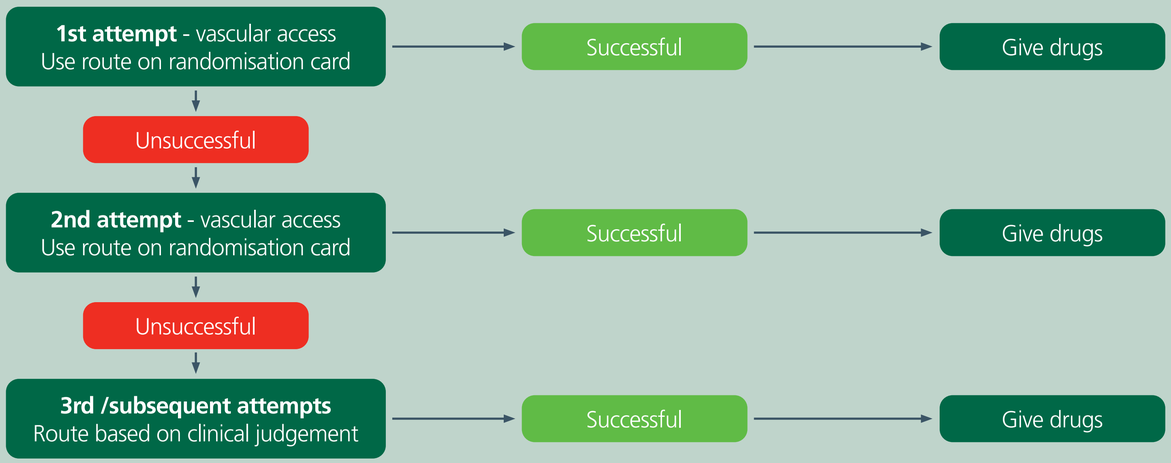
IO
(Intraosseous route)
Participant ID: **RRU-A0001**

Deliver intervention as per randomisation

- After randomisation, you MUST deliver the intervention stated on the randomisation card (unless it would be harmful to the patient). This should be done as quickly as possible.
- Randomisation determines the route that should be used for your first TWO vascular attempts
- If you have been unsuccessful after two attempts, you can decide what route you use for further attempts
- Once vascular access is obtained, you should use it to give cardiac arrest drugs, according to current guidelines

NHS
South Western Ambulance Service
NHS Foundation Trust

Deliver intervention as per randomisation



What to do after you have enrolled a patient

Hospital handover

Inform the hospital the patient has been enrolled in the PARAMEDIC-3 trial.

Please email PARAMEDIC3@swast.nhs.uk if the hospital is not aware of the trial.

Documentation

Please photograph the randomisation envelop

Record on the ePCR in the research tab.

- PARAMEDIC-3
- Envelop randomisation number
- Date/time of randomisation
- Treatment allocation IV or IO
- Number of staff at scene
- Likelihood of possible survivor/ROSC patient being transferred to ICU

Assessment

- At the end of the training, you should complete the online assessment via the QR code. A score of 100% is required to pass and collect a voucher.

Good Clinical Practice Principles – What is Good Clinical Practice?

ETHICAL CONDUCT

- Conduct trials according to the ethical principles originating from the Declaration of Helsinki

RISKS & BENEFITS

- Assess risks & benefits; trial should only start & continue if anticipated benefits justify the risk

PARTICIPANT SAFETY

- Ensure participant rights & safety prevail
- #1 priority

PROTOCOL

- Clear, detailed protocol defining scientifically sound trial (and peer reviewed)

FOLLOW THE PROTOCOL

- Trial must be conducted to approved protocol
- Have a system to deal with and review/monitor non-compliances

RESPONSIBILITY FOR MEDICAL CARE

- The person responsible for medical care of participants must be appropriately qualified. At a recruiting site, this will be the Principal Investigator

DATA PROTECTION/SECURITY

- Everyone involved in a trial must be suitably educated, trained & experienced to perform their delegated task(s)

TRAINING, EDUCATION, EXPERIENCE

- Everyone involved in a trial must be suitably educated, trained & experienced to perform their delegated task(s)

DATA PROTECTION/SECURITY

- Identifiable data must be collected, stored and handled in accordance with the 2018 Data Protection Act (including GDPR)