

ERIC-PPCI FAQs

Version 1 – October 2015

# Screening and eligibility

Who is able to screen patients and consent patients?

Both blinded and unblinded staff are able to screen and take verbal agreement with patients as long as they are allocated these tasks on the delegation log.

However, the blinded staff should be responsible for taking full informed consent once the patient is deemed well enough to do so.

# Randomisation

When the unblinded researcher has confirmed that the randomised treatment has been completed will they need to log back into Sealed Envelope to confirm this?

Yes, the unblinded person will have to log back on to complete the eligibility and intervention data, once intervention has been completed. Both are simple forms to complete and will be demonstrated at the site initiation.

Should the email that the unblinded researcher receives to confirm the randomisation allocation be retained anywhere as a hard copy for eventual archiving?

There is no requirement to print out the email. During randomisation a form is completed on the database and this is saved if access is required at a later date. It is best practice not to print the email out in case it accidentally unblinds someone.

Will the randomisation process auto-generate an email to the other site staff to confirm that a patient has been randomised?

Yes there will be an email to the blinded staff to confirm that a patient has been randomised but it will not include the treatment allocation.

If there was a problem with the first patient and the blinded researcher needed to assist, could they still consent and follow up that patient?

This is a simple straight forward trial and this would be unlikely to happen. As the devices look the same it would be unlikely that unblinding would take place. However it is advised that the blinded nurse should avoid any follow up or data collection for that particular patient if possible.

# Consent

Can nurses take full informed consent?

Yes, as long as this is in line with local R&D policy and the PI has delegated this role to the nursing staff.

What is the time limit for consent?

This should be taken sooner rather than later. It is recommended that this should be obtained as soon as the patient is back on the ward and stabilised particularly if they are involved in the sub studies. All patients should be fully consented prior to discharge or transfer to another hospital.

# Applying RIC/Sham RIC

Can the leg be used instead of the arm?

No, this is much more uncomfortable for the patient and difficult to produce enough ischaemia with the amount of muscle mass. There is also much more supporting data for using the arm.

Will the RIC/Sham RIC device affect the ECG recording?

There is no evidence to suggest that it does.

What happens if the cuff needs to be moved from one arm to the other?

This is fine but should be done during the deflation cycle.

Where should the cuff be placed?

As most PPCI radial procedures are performed on the right arm, it is recommended that the cuff be placed on the upper left arm and the right radial access to be used for angiography. If it is common practice for the paramedics to insert the cannula in the left arm then this should be resited to the right arm.

How are the cuffs packaged and how many cuffs will each site receive?

The cuffs are individually wrapped. The cuffs are single use only, so should only be used once and disposed of as they will not work a second time.

The cuffs come in three sizes (small, medium and large) and each site will receive 5 small, 5 large and 10 medium at the site initiation. Sites should email [ericppci@LSHTM.ac.uk](mailto:ericppci@LSHTM.ac.uk) to request a resupply as necessary.

Many patients do not have a manual BP recorded and the BP is taken from the arterial line. Is this an issue?

Patients need to have a BP recorded prior to starting RIC/Sham therapy. We recommend using the ambulance measurements. We only recommend repeating the BP measurement if the latest ambulance measurement showed a systolic BP >175mmHg. We do not recommend using BP measurements from the arterial line as this would cause unnecessary delays in initiating RIC/Sham therapy.

# ECGs

Do we need to take copies of the ECGs?

Yes, two ECGs for each patient are required, at baseline and post-PPCI. The baseline ECG will generally be an ambulance tracing. The post-PPCI ECG will be the one taken closest to 90 mins after the PPCI.

How should these be saved and sent to back to the CTU?

The ECGs should be photocopied as they are taken. Photocopies are easier to read than scans or faxed copies. The scanned ECGs should be emailed to [ericppci@LSHTM.ac.uk](mailto:ericppci@LSHTM.ac.uk) in batches.

Please name the files as Patient ID\_visit, e.g.

14001\_baseline.PDF

14001\_postPPCI.PDF

Does a 12 lead ECG need to be taken?

No a rhythm print out would suffice.

# CellAegis devices

What happens if the RIC/Sham RIC device fails?

Please contact the CTU at [ericppci@LSHTM.ac.uk](mailto:ericppci@LSHTM.ac.uk) if your device is not working properly. If an error message is shown please consult the manual which is provided with the device.

In addition, each centre will be provided with a manual sphygmomanometer and this can be used as a replacement.

How long does the battery last in the machine?

The devices should be placed in the charging cradles when not in use, however there is sufficient charge in the devices for three back to back interventions.

A manual BP machine will be provided in case the automatic device runs out of batteries or there are 2 patients randomised to the same treatment allocation at the same time.

Is there any way of knowing if the device is not working properly or has not completed the intervention?

Yes, it will bleep to indicate an error. Please consult the manual to identify the error.