

ERIC-PPCI FAQs

Version 3 – June 2016

# 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.

***Who is able to complete the eligibility and trial treatment forms?***

An unblinded member of the team who has signed the delegation log and unblinded training forms.

# 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?

It is best practice not to print the email out in case it accidentally unblinds someone. During randomisation a form is completed on the database and this is saved if access is required at a later date.

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.

***Does the day of STEMI count as day 0 or day 1?***

You should count from the time of admission (door time) as 0. Day 1 would be from time of admission and finish 24 hours later. Day 2 is counted between 24 hours and 48 hours after admission.

# 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.

**If a patient is discharged from hospital prior to fully informed consent being obtained, what are the procedures for collecting this?**

The patient may be contacted by a member of their direct clinical care team, but not the research nurse. It is recommended that a consent form is sent to them in the post along with an information sheet. A covering letter may be added to ask the patient to return the consent form or to contact the research nurse if they have any questions.

Alternatively the patient can be seen at their OPA and consent obtained then. The date on the consent from must coincide with the date that fully informed consent was obtained and not back dated.

***How can I collect data if a patient does not want to be followed up?***

There are three scenarios that may apply;

1. A patient may be willing for their data to be used but does not want to be followed up on the telephone or attend clinic appointments. In that case the follow up can be gathered remotely using their NHS number, hospital records or through their GP. In this case the consent form would need to be fully signed and a note made locally not to follow up the patient.
2. A patient may be happy for the data already collected to be used, but no further data to be gathered. In this case a consent form would still need to be fully signed and an email should be sent to Matt Dodd and Steven Robertson in order to formally withdraw the patient.
3. A patient may wish to have all of their data removed, in which case there is no need for the patient to sign anything. The eCRF consent page should be marked as 'No' giving a reason and an email should be sent to Matt Dodd and Steven Robertson in order to formally withdraw the patient.

# 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.

***Do we leave the cuff on if the procedure ends prior to end off cuff time?***

Yes, the cuff should remain on until the end of the 4 cycles if possible, even if PPCI has completed.

# 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.

**CRF/eCRF**

***If the patient was taken to another hospital first, then transferred, which door time is the one required?***

Door time is the time of arrival at the PPCI centre i.e. your hospital.

***Where should I record medications that are given in the ambulance?***

This can be recorded in the Pre Procedural and Peri-procedural Drugs under the Index Admission form.

***The LVEF value has been reported as 25-30%, how do I record this in the eCRF***

When LVEF is reported as a range rather than a single value it is better to record this as the midpoint value on the eCRF with an explanatory note in the notes section e.g value reported is 25% - 30%, recorded 27% in the eCRF. The reason for this is that it is very difficult to include ranges in the statistical analysis of the data.

***I can’t save a form in the eCRF as the data is incomplete***

A draft version of the form can be saved by waiting 10 seconds within the form and then clicking “return to patient”. A pop-up box will appear and “OK” should be clicked. When the additional data is received, click to “add” the form and then “load draft”. The additional data can be added and the form saved. Please note though that the data is not submitted until you enter your password to save the form and the form will continue to appear as overdue until it is submitted.

***I’ve noticed a mistake on the form that is already saved***

Edits to the eCRF can only be made by Matt or Steve. Please “Create a query” within the form outlining the changes required and we will make the amendments.

***What point are the follow-ups measured from***

Follow up is measured post-randomisation, not post PPCI or post discharge.