



RECAST-3 FAQs

General FAQs

When are you expecting to restart site set-up?

Due to an issue with the original devices, we are now on board with a new company providing an alternative RIC device. We have REC approval and are about to submit to MHRA for approval. We are hoping to set sites up and commence recruitment in early 2022.

How many participants are you expecting each site to recruit?

Sites should recruit approximately 21 patients over the 33 months of recruitment (less than 1 per month).

What is the planned recruitment end date?

This will depend on when the devices are ready and when we can start recruitment. The plan currently is to set sites up early autumn with a view to start recruitment in December 2021. Recruitment is scheduled for 33 months, so would therefore end in September 2024.

Will we be able to take part if we are recruiting into ATTEST-2?

Yes – you will be able to take part in RECAST-3 even if you are currently recruiting to ATTEST-2, though you cannot co-enrol participants. ATTEST-2 is in the later phase of the trial and therefore coming up to the end of recruitment; RECAST-3 will allow non-medical consent which may allow further inclusion of patients that may be otherwise missed.

Are the research team able to obtain consent?

Yes, we do not need a medic to take consent. Those trained in GCP and the trial procedure, and on the delegation log can consent. You must however have a medic on the delegation log who can review and sign off SAEs.

Who will conduct the day 90 follow-up?

The day 90 follow-ups will be conducted centrally by the Follow-up Coordinator in Nottingham. Participants will be contacted by telephone with a postal back-up form if the participant cannot be contacted. Prior to the postal form being sent out, the site research team will be contacted to confirm the participant's details.

Can the day 2 NIHSS score be completed by ward staff?

This should be completed by the research team where possible. However, if the day 2 data falls on a weekend and research staff were not available, it would be preferable to use the score collected by the clinical staff (as per standard of care) rather than to wait until the next working day.

Scan FAQs

Does the repeat CT scan need to be performed after both treatment doses on day 2 have been given or can it occur before/in-between treatment?

Ideally the scan should be performed on Day 2, the day after their stroke. However, if a clinical scan is indicated beforehand, we wouldn't expect a further scan to be performed.

Does the repeat CT scan require review immediately after execution (e.g. over the weekend?)

The next working day is suitable

Device FAQs

When will the devices be delivered to sites and how many per site will we receive? We are expecting delivery of the devices in autumn and will be sending these out to sites shortly after – we will be supplying 1 RIC device and 1 sham device per site (each device will come with 3 varying cuff sizes and 2 chargers).

We will be restricted to only recruiting Monday to Thursday, as research nurses do not work on a Saturday here at our trust, so will be unable to deliver the intervention if a patient is recruited on a Friday. Will this impact on our involvement?

As long as the ward staff have been trained in trial procedures either by attending the SIV or completing online training and have watched a shortened GCP training video that we will be producing, they can apply the device out of hours. This also includes non-nursing staff such as health care assistants who are also able to deliver the intervention if appropriately trained as above. **Please Note:** ward staff will not be able to obtain consent or randomise patients.

Do you anticipate any problems with compliance due to the length of time and repetitiveness of the intervention, especially in cognitively impaired patients?

We have trialled remote ischaemic conditioning in 2 separate studies and there have been no significant issues with compliance. However, this larger study will also look at whether the device is well-tolerated in stroke patients.

If we need to take the patient's BP in the 5-minute rest cycle, at what point can we take the machine off and record the BP?

The machine will automatically re-inflate after 5 minutes. The cycles cannot be paused unless the machine is switched off - restarting the machine will restart the cycles. The reperfusion period in the arm is an important phase and we would prefer that the other arm is used instead.

Can the device be stopped part-way through the cycle?

No - there is no pause button on the devices so if you stop the treatment for any reason, when you switch it back on it will re-start the 4 cycles. We would ask that you eliminate as many potential reasons to stop as you can before you start the device. If the machine does need reactivating half-way through the cycles for any reason, you will need to remember to **switch the device off after the 4th cycle** (otherwise the machine will run through to the end of 4 *more* cycles after re-activation).

Does the person delivering the intervention need to remain with the patient for the duration of the treatment (approx. 40 mins)?

Yes - the participant should not be left alone. The investigator should be in the local vicinity, i.e. in the bay and be able to view the participant at all times while receiving the treatment. (This is a good opportunity to complete trial paperwork simultaneously!)

In the previous studies, were there any reports of increased bruising with the trial intervention for those patients who had received thrombolysis? A degree of petechiae is not unusual (even when a BP is taken). This did not raise any safety concern in RECAST-1 and RECAST-2 in terms of neurovascular compromise of the limb. We will still be monitoring safety events, but we will only require the events reporting that meet the seriousness criteria.

What are the timings for delivering the intervention?

There are 4 doses in total (2 per day), with each dose consisting of 4 cycles:

- On day 1, the first dose must be delivered within 6 hours of the onset of the stroke, which is then followed by the 2nd dose 1-2 hours after the end of the first dose.
- On day 2, two doses of the RIC or sham are applied - once in the morning and once in the afternoon (there is no specified time from randomisation).

Is there a maximum BP for inclusion?

There is no upper BP limit in the exclusion criteria, however a pressure limiting pop-off relieve valve is included in the RIC device to ensure the cuff is never inflated above a pre-set pressure of 300mmHg. This would not usually be seen in clinical practice and the majority of centres would lower BP for clinical reasons if it was this high.

If the participant finds it uncomfortable to keep the cuff on the same arm, can we alternate arms between cycles or doses?

TBC

Funding FAQs

What is the payment per participant?

£52 – a combination of £40 per recruit and £12 for nurse administration time (of the sham).

Is there a payment for archiving?

Yes, a one-off £200 payment at the end of the trial.

Will sites be paid for performing the 2nd CT scan?

There is no funding for the repeat CT scan on day 2. In the majority of cases, the second scan will be performed for clinical reasons (post rtPA or MT). It is also performed for safety reasons, even in the non-thrombolysed participants due to potential anti-platelet effects of RIC. Therefore, if the second scan is not performed for clinical reasons, then it is performed for safety reasons and considered a **service support cost (SSC)**. This was discussed and approved with the local CRN prior to the grant application. Sites to liaise with their PI and R&D team to establish whether the 2nd CT scan will be feasible.

Is there costing to provide to the PACS teams for providing the scans onto DISCs for uploading?

Yes, there will be a payment for the upload of scans (this is part of the £52 per recruited participant).

What are the Excess Treatment Costs (ETC) associated with the trial?

ETCs that should be covered by site amount to £87.30 per recruit. This is a combination of £75 for the RIC device and £12.30 per nurse administration time. This should be claimed through the trust's ETC threshold. For sites that have already reached their ETC threshold, this cost will need to be paid by NHS England. We need to know how each site will pay prior to setting up.