

## STANDARD OF CARE – PATIENT INFORMATION

### Importance of the “Standard Care” Control Group within the LACI-3 Trial

Some of our participants in the LACI-3 trial will be assigned to the control group. This group will not receive either of the study drugs, Cilostazol or Isosorbide Mononitrate (ISMN), and we do not use a “dummy tablet”, otherwise known as a “placebo tablet”, in LACI-3.

However, those assigned the control group in the LACI-3 trial will receive the current and best-known stroke prevention treatment according to international guidelines, sometimes called “Standard of Care”, that is currently available within the UK and the rest of the world. This guideline-based “Standard of Care” is based on the results of many clinical trials, involving 1000s of patients over the last 40 or more years. “Standard of Care” includes tablets to stop small blood clots forming (like aspirin), to lower blood pressure, and to lower the level of fat or lipid in the blood, since we know that these tablets together help to stop more strokes.

### Study Groups in LACI-3 Trial

1	2	3	4
<b>Cilostazol</b>	<b>Isosorbide Mononitrate</b>	<b>Cilostazol &amp; Isosorbide Mononitrate</b>	<b>No study drugs Control Group</b>
			

### Why is the Control Group important?

Participants in the “Standard of Care” control group will receive the best current stroke prevention treatment available, including lifestyle advice to help reduce smoking, increase exercise, healthy diet and good sleep patterns, and thus help to improve their long-term outcomes.

We do not know if the two drugs that we are testing in LACI-3 will be better or not than “Standard of Care” treatment.

Having a “Standard of Care” control group is vital to compare if the current guideline-based treatment leads to better outcomes than do either or both of the two drugs that we are testing in LACI-3. Receiving “Standard of Care” could be the best treatment option available. We will not know this until we have finished recruiting all the participants, they have all completed the follow-up, and we have analysed the data to draw conclusions from the results.

### Why does LACI-3 not use a placebo “dummy tablet”?

LACI-3 does not use a “dummy” or “placebo” tablet as there are no identical appearing “dummy tablets” available for the two drugs being tested. There are “dummy tablets” that look different, but these are very expensive, and would not make LACI-3 any better. This is because two major organisations, the [National Institute of Health Research](#) (NIHR), who provide the money for LACI-3, and the [Medicines and Healthcare Products Regulatory Agency](#) (MHRA), the experts in licensing new drugs, both said that a “dummy tablet” would not help and was not necessary. Therefore, LACI-3 is using the best trial design.

### **Benefits for All Groups**

Once a patient in the trial passes the 4-week period, they will only be contacted at 6-, 12- and 18-months intervals. Therefore, participating in any of the groups means you are getting the best current treatment, advice and care from being in the trial than if you had not joined.

### **Resources**

There are a range of resources available which, you can access from the link below. It includes advice for eating well after stroke, key measures for improving and maintaining cardiovascular health and self-evaluation to assess your brain score:

[Resources | LACunar Intervention Trial-3 \(LACI-3\)](#)