

# Participant Facts Sheet



Assessment of efficacy and safety of cilostazol and isosorbide mononitrate to prevent adverse outcomes in patients with cerebral small vessel disease (lacunar) ischaemic stroke.



Academic and Clinical Central Office for Research and Development



Local research team's NHS institution logo goes here

## We invite you to take part in the LACI-3 study

In this leaflet:

- Why are we inviting you?
- Essential information
  - Why are we doing this study?
  - What is LACI-3?
- What does LACI-3 involve?
- How can I make a decision?
- More information
- About us

## Why are we inviting you?

According to our records, you may be eligible for our study because:

- You have had a lacunar stroke in your brain.

We plan to test if two drugs called **cilostazol** and **isosorbide mononitrate** can prevent problems with thinking, memory, more strokes and mobility, and dementia, which can occur after a lacunar stroke.



**Please read this summary to help you decide.**



Do ask any questions you may have.

# Here is a diagram of essential information about the study



You have had a lacunar stroke in your brain



A doctor has invited you to take part  
You have time to decide and ask questions



You get guideline standard medical care  
if you do or don't take part



If you decide to take part,  
you sign the consent form



Random allocation to one of the four groups:



## 1. START



- Cilostazol

## 2. START



- Isosorbide  
mononitrate

## 3. START



- Cilostazol
- Isosorbide  
mononitrate

## 4. NO STUDY DRUGS



Everyone continues usual guideline medical drugs.



The research team will contact you every 6 months to see  
how you get on and post a supply of drugs, if allocated to it.

## Why are we doing this study?

- Lacunar stroke survivors are at risk of problems with thinking, memory, and walking and can sometimes lead to dementia.
- Lacunar strokes are caused when small blood vessels deep within the brain become damaged and do not work as well as before.
- There are no treatments yet to help the small blood vessels work better. As a result, damage to the brain may continue to build up.
- We have found **two drugs** that we think may reduce damage to the small blood vessels in the brain and therefore could prevent strokes and thinking problems due to small vessel disease.
- **Cilostazol** and **isosorbide mononitrate** were safe and well tolerated in patients after lacunar stroke in the LACI-2 study of 363 people.

## What is LACI-3?

- LACI-3 is a randomised controlled study.
- Participants will be randomly assigned to one of the **four** groups:
  1. They may be given **cilostazol** only.
  2. They may be given **isosorbide mononitrate** only.
  3. Both **cilostazol** and **isosorbide mononitrate** will be given.
  4. Neither **cilostazol** nor **isosorbide mononitrate** is given.
- Everyone gets guideline standard medical care.
- LACI-3 will tell us what future best medical care is.

## What does LACI-3 involve?

### Consent

It is up to you to decide whether you take part.

If you don't want to, that's OK.

Your decision will not affect your standard medical care.

### Randomisation

A random choice as to which drug(s) you will take or not.

### Follow-up

The study will follow-up with you by phone and post for **18 months** every 6 months to see how you get on and provide a supply of drugs, if allocated to.

# How can I make a decision?

- If you are interested in hearing more about the LACI-3 study, one of our team will go through this information with you.
- We will discuss:
  - What are your treatment options?
  - What is important for you?
  - What will happen if you take part in LACI-3?
  - What are the possible benefits of taking part?
  - What are the possible disadvantages of taking part?

## More information

### If you are interested:



Read the participant information sheet.



Visit our website [www.laci-3.ed.ac.uk](http://www.laci-3.ed.ac.uk)



Ask if anything is unclear, to help you decide what's right for you.  
Please feel free to talk to others about this study and invite them to take part in your outpatient appointment if you wish.

## About us

### Funder:



### Run by:



THE UNIVERSITY  
of EDINBURGH



The University of  
**Nottingham**

**Thank you for reading this information and considering taking part.**