## Impact of the VICI Trial

The information from this trial is important for eye doctors to decide how to treat people with CSCR. The trial has shown that there is no benefit of taking eplerenone if you have persistent CSCR.

The trial also provides new and important information on how long it takes for chronic CSCR to resolve and then return which will help doctors better inform patients of what to expect.

Researchers will continue to look for the best ways to treat people with persistent CSCR.

The results will be published in a medical journal and on the NIHR website https://www.journalslibrary.nihr.ac.uk

## For further information

- If you have any questions for your local hospital VICI research team please phone <Insert contact details>
- If you have any questions about how the trial was conducted please contact the trial management team, email: vici-trial@bristol.ac.uk
- Blood samples donated at the start of the trial are stored in the University of Southampton biobank under the care of Prof Andrew Lotery, chief investigator of the trial. Please phone 023 81208948 with any questions.
- For **general information on CSCR** visit https://www.macularsociety.org/central-serous-retinopathy
- For **general information on clinical research** visit: www.ukcrc.org/public-awareness-of-clinical-research/information-resources-on-clinical-research

## Thank you for your participation in the trial

This project is funded by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR partnership. The views expressed in this publication are those of the author(s) and not necessarily those of the MRC, NIHR or the Department of Health and Social Care.
The EME Programme is funded by the MRC and NIHR, with contributions from the CSO in Scotland and Health and Care Research Wales and the HSC R&D Division, Public Health Agency in Northern Ireland.

FUNDED BY NIHR | National Institute for Health Research

VICI TRIAL

STUDY ID: <XXXXXX>

# Summary of the results of the VICI Trial

**THANK YOU** for taking part in the VICI Trial. Without you the trial would not have been possible. This leaflet contains the results of the trial, the group you were allocated to (eplerenone or placebo) if you asked to know it, and details of where you can find further information.

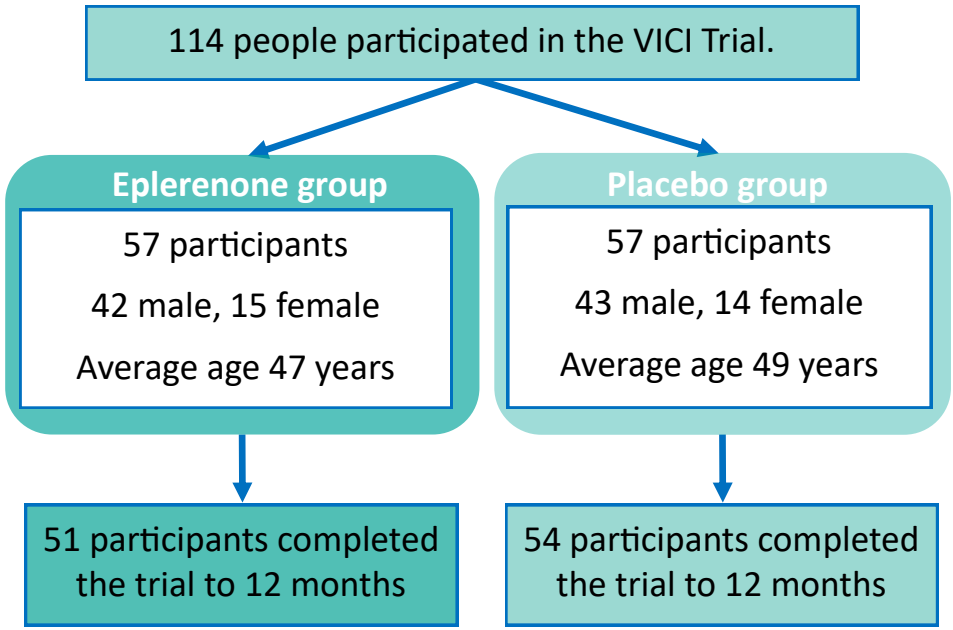
## The main aims of the VICI Trial were...

- To see if eplerenone is better than placebo for improving vision in people with persistent central serous chorioretinopathy (CSCR).
- To see if there were any changes in the amount of fluid in the back of your eyes after taking eplerenone or placebo.
- To look at the safety of eplerenone by collecting information on illnesses you experienced during the trial.
- To find out more about how long it can take for persistent CSCR to resolve when taking eplerenone or placebo.
- To see how often CSCR recurs in people who got better.

## Design of the VICI Trial

One hundred and fourteen people with persistent CSCR participated in the trial. This was calculated to be enough to find a difference between the groups, if there was one. Participants received eplerenone or placebo tablets once daily for up to 12 months.

Participants were put in to either the eplerenone or placebo group at random using a computer system. No one directly involved in the trial knew what group participants were in. This was so we could fairly assess whether eplerenone was effective for treating CSCR.




EITHER: You were allocated to receive <EPLERENONE> <PLACEBO>. Please see overleaf for details of where you can find further information.

OR: You requested not to know which group you were allocated to. You are able to change your mind at any time. If you want to know whether you were taking eplerenone or

## VICI Trial results

**The main study result showed that eplerenone was no better than placebo for treating CSCR. There was no difference between the groups in the number of letters people could read with their affected eye under normal lighting.**

- We also did not find a difference between the groups in the number of letters people could read in low light (the test where a darker filter is placed in front of your eye).
- We found the amount of fluid in the back of the eye reduced more in the placebo group than the eplerenone group.
- We found that CSCR resolved completely (i.e. all fluid disappeared) in nearly half of people in the placebo group and a third of people in the eplerenone group at some point during the 12 month trial.
- There were no safety concerns with taking eplerenone.

**Eplerenone was no better than placebo in any of the trial tests.**

Based on what we observed among all people in the trial who had persistent CSCR, we estimated that:

(a) CSCR is likely to resolve in half of all affected people within 2 years, but;

(b) CSCR is likely to recur in half of all people in whom it resolves by about 6 months after it resolves.