Short participant information leaflet

Edoxaba**N** fo**R** **I**ntra**C**ranial **H**emorrhage survivors with **A**trial **F**ibrillation (ENRICH-AF)

ENRICH-AF

IRAS reference number: 277102 **EudraCT number:** 2019-002075-33

Sponsor: Population Health Research Institute HEALTH THROUGH KNOWLEDGE **UK Coordinator:** THE UNIVERSITY of EDINBURGH

Your local team is from:

HSC Western Health and Social Care Trust

We invite you to take part in the ENRICH-AF research study

Joining this research study is entirely up to you. Please read this summary, which will help you decide. One of our team will go through this information leaflet with you. They will help you decide whether or not you would like to take part and answer any questions you may have. This should take about 15 minutes. This leaflet summarises the purpose of the research and what will happen if you take part. If the summary interests you, you can read the supplementary leaflet, which provides more detailed information. Do ask if anything is unclear. You can find information about how to contact us at the end of the supplementary leaflet. Please feel free to talk to others about this research study if you wish.

Here is a diagram of essential information about the research

You had a stroke due to bleeding

↓

You also have an irregular heartbeat

↓

Doctor has checked that you can take part

You have time to decide and ask questions

↓

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

↓

If you decide to participate, you sign the consent form

↓ (dashed) ↓ (solid)

Optional extra brain MRI scan

↓

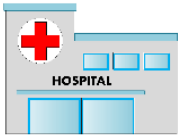
ENRICH-AF

Random allocation to start/not start Edoxaban. A member of the team at your hospital will tell you which treatment approach ENRICH-AF allocates you to.

50% 50%

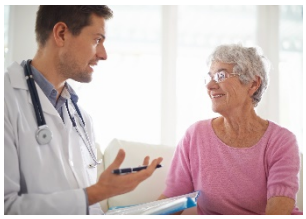
START Edoxaban ↓

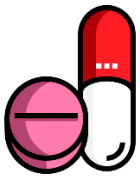
DO NOT START Edoxaban ↓



The research team will invite you to the clinic every 6 months to see how you get on and provide a supply of Edoxaban, if allocated to it.

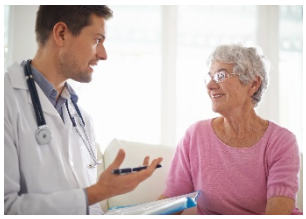
You can change treatment or withdraw at any time

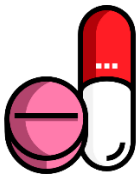



Here is the essential information in more detail

- **Why are we inviting you?** You and your doctor have agreed that you might benefit from treatment for atrial fibrillation, or "AF" for short. AF can cause clots to form in the heart. These clots may travel to the brain, block a blood vessel, and cause a stroke. "Anticoagulant" blood-thinning drugs, like Edoxaban, help people with AF by reducing the risk of stroke, despite increasing the risk of bleeding. We do not know whether it is better for people like you with AF after a bleed within the skull, known as a "brain haemorrhage", to start, or not start taking Edoxaban (an anticoagulant drug).
- **Why are we doing this research?** We want to find out whether starting or not starting Edoxaban is better for people like you.
- **What is ENRICH-AF?** ENRICH-AF is a randomised controlled trial. This type of research is the fairest test of a treatment. In this trial, one group of people starts Edoxaban and the other group does not start Edoxaban. You would have a 50% chance of going into one or another group. You will know which group you go into. We will then study how the two groups of people get on to work out what's best. Research like this helps to continually improve the treatments and care provided to all patients now and in the future. The risk of participating in this study is low apart from the known side effects of Edoxaban. If we find that




one treatment group does better than the other, the trial will be stopped. Your treatment could then be changed to the treatment approach that is found to be best.

- **What happens now?** 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.
- **If you decide not to take part**, you and your doctor will agree on whether you start Edoxaban. This may be the same as the treatment you would have received by taking part in this research.
- **If you decide to take part** you must sign a consent form. You can have an MRI brain scan before entering the trial. ENRICH-AF will randomly assign you to either START Edoxaban or NOT START Edoxaban.
  The research team will check how you get on every 6 months at the clinic and provide a 6-monthly supply of Edoxaban if allocated to it.
  Your information will be kept strictly confidential by the study team.
  You are free to withdraw at any time, without giving a reason, by contacting the ENRICH-AF team.
- You can find out more about the ENRICH-AF research study from the supplementary participant information leaflet, or by talking to us.

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