Participant Information Sheet

Antiplatelet Secondary Prevention
International Randomised study
after INtracerebral haemorrhaGe.

Local research team's NHS institution logo goes here

We invite you to take part in the ASPIRING study

You should have been given the opportunity to watch the ASPIRING video (via www.ASPIRING.ed.ac.uk) and read the ASPIRING Fast Facts.

In the video and Fast Facts, we explained why you have been invited to take part. We provided you with information about brain haemorrhage and its risks. We explained why we are doing the study and what will happen if you take part.

- This leaflet aims to help you decide whether to take part.
- It is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully.
- Talk to others about the study if you wish.
- Contact us if there is anything that is not clear, or if you would like more information.
- You can ask questions or provide consent face-to-face in person, via an approved video conferencing system, or by telephone.
- Take all the time you need to decide whether you wish to take part.

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What is the purpose of the study?

Having a brain haemorrhage increases your risk of clotting problems**.**

- Stroke due to bleeding into the brain, known as “brain haemorrhage”, affects more than 3 million people in the world each year.
- In total, there are more than 20 million brain haemorrhage survivors in the world. 86,000 of them are in the UK.
- People who survive brain haemorrhage are at double the risk of suffering heart attack or stroke due to blood clotting, when compared with people of the same age and sex without brain haemorrhage.
- Doctors try to prevent these problems by using medicines that lower blood pressure.
- Despite taking blood pressure-lowering medicines, heart attack or stroke due to blood clotting affect about 1 in 10 brain haemorrhage survivors every year.

> “Despite best standard medical care, brain haemorrhage survivors remain at risk of stroke, heart attack, and other bleeding and clotting problems. We are aspiring to find out if **aspirin** or **clopidogrel** can prevent these problems after brain haemorrhage.”
>
> **Professor Rustam Salman, ASPIRING Chief Investigator**

What is this research study about?

Studies called randomised controlled studies are the fairest tests of treatments.

- These studies found that people who have had a heart attack or stroke benefit from antiplatelet medicines like aspirin and clopidogrel.
- These medicines thin the blood and prevent blood clotting problems, but they may increase the risk of bleeding slightly.
- Overall, these medicines do more good than harm, so they are used in standard medical practice to prevent blood clots.

Many strokes and heart attacks that happen after brain haemorrhage are caused by blood clots, so **aspirin** or **clopidogrel** might help to prevent them. However, doctors aren’t sure whether aspirin or clopidogrel can be used for people who have had a brain haemorrhage.

- That’s why we did a study called the REstart or STop Antithrombotics Randomised Trial, known as “RESTART”. RESTART was a randomised study involving 537 survivors of brain haemorrhage in the UK. People taking part had diseases that block blood flow due to clotting.
- RESTART split these people into two groups: half were encouraged to start **aspirin** or **clopidogrel**, and half were encouraged to stay off antiplatelet medicines.
- We were pleased to find that fewer people in RESTART who started aspirin or clopidogrel had another brain haemorrhage compared to people who kept off antiplatelet medicines. Aspirin and clopidogrel also seemed to cause fewer major vascular events.

- You can get find out more about RESTART at www.RESTARTtrial.org.
- RESTART's results are promising. But a bigger randomised controlled study is needed to find out if adding aspirin or clopidogrel to standard care is acceptably safe and helps a wide range of brain haemorrhage survivors, compared with standard care alone.

This study is called **ASPIRING**, which stands for, "Antiplatelet Secondary Prevention International Randomised study after INtracerebral haemorrhaGe"

- ASPIRING will be the largest and most reliable study of aspirin and clopidogrel after brain haemorrhage. It will involve more than four thousand people worldwide.
- This study aims to produce reliable information about whether aspirin or clopidogrel help people after brain haemorrhage. The findings of ASPIRING could affect how doctors treat people with brain haemorrhage in everyday medical practice worldwide in the future. If ASPIRING shows that aspirin or clopidogrel works, this could prevent another major vascular event for thousands of brain haemorrhage survivors worldwide each year.

Why have I been invited to take part?

We invite you to take part because you have suffered a stroke due to bleeding in your brain and you are not taking any medicines that thin your blood now.

Do I have to take part?

- No, it is up to you to decide whether to take part.
- If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form.
- You can give your consent by telephone or video call later if that's easier for you.
- If you decide to take part, you are still free to withdraw at any time and without giving a reason.
- Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

Information and consent

One of the study team at your hospital will go through this information sheet with you and answer any questions you have. This should take about 15 minutes.

If you wish, talk about this research study with people you know, such as your relatives or carers, and take as long as you need to decide.

If you agree to take part, we will ask you to sign a consent form. We will give you a copy of the signed consent form and this participant information sheet either in person or we can email them to you.

Whatever you decide about taking part, you will receive the same standard medical care in addition to the study medicine, if you are allocated to take it.

Collection of information about you and your medical history

One of the study team will ask you some simple questions about your health, collect some information from your medical records, and send a copy of your brain scan to the University of Edinburgh so that they can study whether people respond differently to aspirin according to the appearances on their scan.

They will record your contact details and the contact details of the close personal contacts you identify who have agreed to provide information about how you get on; we may need to use these if new safety information becomes available, or the study is stopped.

Everyone registered with a GP has their own unique number. This is known as a CHI number in Scotland and an NHS number in the rest of the UK. We will collect your CHI/NHS number because it helps us to identify you correctly for follow-up.

Random allocation to treatment

Randomised studies are the fairest tests of treatment because the process of randomly allocating each patient to a group makes the groups very similar, so that it is fair to compare them to see which one does better. The chance of being in either group is equal, or 50%, also known as “50:50”, meaning:

You are as likely to be assigned to **starting aspirin** or **clopidogrel** as you are to be assigned to **not take antiplatelet medicines**.

- We do not choose who gets which treatment.
- The only thing that should differ between the two groups is the treatment that is being studied.
- You will receive standard care whichever group you are in.
- In ASPIRING, your study team sends some information about you in confidence to the ASPIRING coordinating centre in Edinburgh; this is described below in the section, "How will we use information about you?"
- Next, the computer system randomly allocates you to a policy of starting aspirin or clopidogrel, or not starting antiplatelet medicines.
- You will know which treatment you are allocated to.
- If you are allocated to start aspirin or clopidogrel, you will be prescribed the drug chosen by your hospital consultant to start within one day as a daily tablet that you take by mouth.
- They will write to your general practitioner (GP) and other doctors caring for you to let them know that you are taking part, so that they will continue the treatment that the study has allocated you to until the end of the study.

Adherence to treatment

It is important that you stick to the treatment group you are assigned to, so that the study's results are reliable. However, this can change after discussion with your doctor if you experience a side effect or develop a new health problem that your doctor confirms means a blood thinning medicine should start or stop.

Checking how you get on in the future

- The study needs to know how you get on so that it can work out which treatment group is best. You will not need to come back to hospital.
- When you leave the hospital, or move to a rehabilitation unit, the doctors at your hospital will send the ASPIRING coordinating centre information about your health and where you are moving to.
- ASPIRING will keep an eye on your progress by receiving information about hospital admissions, drug prescriptions, drug dispensing, death records and other data held by NHS bodies such as NHS England that could help us work out whether starting or avoiding antiplatelet medicine is best.
- The ASPIRING team will send your details (date of birth, postcode, hospital number, and NHS / CHI number) regularly to NHS England and other NHS bodies in Scotland and Wales, who will link this information with your health records, and send it back to us, so that we know how everyone in the study is getting on.
- **So, we will not ask you back to hospital for regular follow-up visits.**
- We intend to follow every person in the study for between one and five years until the end of the study. We will store this information securely and confidentially at The University of Edinburgh for 5 years after the end of the study.

Other drug studies

If you enrol in ASPIRING, you can enrol in other randomised controlled studies of other drugs if both studies agree that you may take part in them at the same time.

What happens to my usual medicines?

Your doctor will consider whether any of your medicines need to be changed if ASPIRING assigns you to the group taking aspirin or clopidogrel. If not, you can continue to take your usual medicines.

Pregnancy

- If you are a woman of childbearing potential, you must have a negative pregnancy test before taking part in this study.
- If you are not pregnant, or you are breastfeeding, you must use at least one of these highly effective birth control methods: combined (oestrogen and progestogen containing) hormonal contraception that prevents ovulation, progestogen-only hormonal contraception that prevents ovulation, intrauterine device, intrauterine hormone-releasing system, occlusion of both Fallopian tubes, male partner who has had a vasectomy, or sexual abstinence.

What if relevant new information becomes available?

If new information becomes available which might influence whether you should continue to take part in the study, we will contact you by email or post.

Will I be paid for taking part?

You will not be paid for taking part. You also won’t benefit financially if study results/data are exploited for commercial gain.

Is there anything I need to do or avoid?

If you are allocated to the policy of taking aspirin or clopidogrel: you must store it safely at home and do not share it with anyone else who shares your living space.

If you are allocated to standard care and avoid antiplatelet medicines: you should not take aspirin or clopidogrel unless you develop a new health problem that your doctor confirms needs treatment with a blood thinning medicine.

What are the possible benefits of taking part?

There are no direct benefits to you from taking part in this study.

The results from this study will help us to treat others in the future.

What are the possible disadvantages of taking part?

Disadvantages of medicines in standard practice

- The study team will explain that the risks of the antiplatelet medicines used in ASPIRING are the same as in standard practice.
- The common side effects of aspirin are an increased bleeding tendency and indigestion.
- The common side effect of clopidogrel is an increased bleeding tendency.

Disadvantages of the study

You may find the time you spend completing study visits inconvenient.

Before deciding to take part, you should consider if this will affect any insurance you have and seek advice if necessary. Taking part in clinical research may affect the insurance cover you get (e.g. travel insurance, life insurance, critical illness cover). Before taking part, seek advice if you need it.

What if there are any problems?

- If you have a concern about any aspect of this study, please refer to the contact details at the end of this document to identify the most appropriate person to answer your question.
- In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the NHS organisations at the end of this document but you may have to pay your legal costs.
- The normal NHS complaints mechanisms will still be available to you (if appropriate).

What will happen if I don't want to carry on with the study?

If you decide to withdraw, please contact your local study team. ASPIRING will retain information collected about you before the time you withdrew.

What happens when the study is finished?

Anonymised information about you will be kept indefinitely so that researchers can look at it again.

This will enable us to study the effects of aspirin and clopidogrel in the long-term. It will also enable us to address other relevant research questions that we might not have thought of now without having to repeat this study all over again.

After the study is over, whether you continue aspirin/clopidogrel or not will be at your discretion. You should discuss this with your GP because your decision may be influenced by the findings of ASPIRING.

Will my taking part be kept confidential?

All the information we collect during the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

ASPIRING is run by a team at the University of Edinburgh who take care to protect your information. The information is processed and protected by this team. The team includes medical, computing and administrative staff, all of whom have a duty of confidentiality to you. Identifiable information about you will be sent in confidence via secure NHS networks to the ASPIRING coordinating centre in Edinburgh.

Identifiable data about you, described below, will be kept in a separate part of the study database from your health information.

Your information (your personal data) will be stored securely in a study database on servers, which are securely hosted by the University of Edinburgh. Contact information for your nominated representative will be stored within your NHS records by your direct clinical care team. The study database will be compliant with the relevant regulations and Sponsor Standard Operating Procedures. Only trained and approved members of the study team will be given password-protected access to the study database. We comply with the GDPR and Data Protection Act 2018 and Caldicott principles when sharing or processing your data within the NHS and other organisations involved in the study. The University of Edinburgh/NHS Lothian is the data controller.

How will we use information about you?

We will need to use information from you and your medical records for this research project.

We will collect your CHI number or NHS number. Note that the CHI is a population register, used in Scotland for health care purposes. The CHI number uniquely identifies a person on the register and is personal identifiable information. Your CHI number or NHS number is being collected to allow us to identify you in your medical records.

Other personal identifiable information collected will include:

- Your name
- Date of birth
- Address, telephone number and email
- Sex assigned at birth
- Ethnicity
- Relevant medical Information
- Some socioeconomic Information
- Contact information for the representatives whose agreement you have obtained to be nominated

This information will be stored securely and accessed only by those authorised to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number assigned instead.

We may access information about how you are getting on from other sources such as the Office for National Statistics (ONS) / National Records of Scotland (NRS), the NHS central register, and other registries including those managed by NHS England, Public Health Scotland, and the SAIL databank in Wales. We will identify you when we communicate with your GP about how you are getting on, to make sure that we are communicating about the correct person. Hospitals involved in ASPIRING may be required to provide information for official inspections of research conduct made by the sponsor of the study or other regulatory bodies. All identifying information will be removed before the data are analysed. We will not identify you in the report of the study's results that we submit to a medical journal. You have the right to check the accuracy of information held about you and correct any errors.

The data you provide to us is important and may be useful to other research studies for several reasons: this ensures that research is open to peer scrutiny, optimises the use of good quality research data, supports policy and other decision-making, and allows researchers to explore whether new ideas during or after the study might be true by re-examining data. So that your data can be used anonymously for further research in the public interest, an NHS organisation will replace your identifying details with a unique anonymous code. This will enable your data to be linked to routinely-collected data, including your health records. The data can then be used for research in anonymous form in a secure environment.

International Transfers

We may share de-identified information from ASPIRING about you outside the UK for research related purposes to other researchers anywhere in the world to help answer related research questions. If this happens, we will only share the data that is needed. We will also make sure you cannot be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with hospitals or higher education institutions, who have signed a data sharing contract.

We will make sure your data is protected. Anyone who accesses your data outside the UK must follow our instructions so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- Some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK.
- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website.
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.

- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the ICO website.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records. If you do not want this to happen, tell us and we will stop.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you agree to take part in this study, you will also have the option to allow the research team (within the sponsoring organisation) to securely store your contact details and agree to be contacted about other ethically approved research studies. You will only be contacted by a member of this research team to determine if you are interested in taking part in another research study. Your verbal consent may then be sought to pass your contact details to another research team within the University of Edinburgh and/or NHS Lothian. Agreeing to be contacted does not oblige you to participate in further studies.

Where can you find out more about how your information is used?

You can find out more about how your information is used:

- in a leaflet available at www.hra.nhs.uk/patientdataandresearch
- by asking one of the study team (see the last page of this sheet)
- by sending an email to dpo@ed.ac.uk (University of Edinburgh Data Protection Officer)

What will happen to the results of the study?

The results of the study will be submitted for publication in professional journals.

We will not contact you individually when the trial ends, but we will publish information about study progress and make the final results available in a format appropriate to the general public on our ASPIRING website: www.ASPIRING.ed.ac.uk. When the results of our study are published, we will not include any individual information that would identify you personally.

Who is organising and funding the research?

THE UNIVERSITY *of* EDINBURGH

NHS Lothian

- The University of Edinburgh and NHS Lothian sponsor the study.
- The British Heart Foundation fund the conduct of ASPIRING by a grant to the University of Edinburgh.
- Professor Rustam Salman is the Chief Investigator in charge of the study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests.

This study has been reviewed and given a favourable opinion by the Scotland A Research Ethics Committee. All participants are covered by The University of Edinburgh's insurance policy, which needs to be in place before the study starts.

In designing this study, we have taken into account patients' opinions on what's involved in the study. The Research to Understand Stroke due to Haemorrhage (RUSH) patient reference group, and other patients, have reviewed and commented upon this participant information leaflet. You can find information about the RUSH patient reference group here: www.RUSH.ed.ac.uk.

Thank you for taking the time to read this leaflet, and for thinking about taking part in ASPIRING

Who can I contact for more information?

You can contact your **local study team** about your participation:

Insert Name, Insert Job title

Insert address, address, address, address, address, address, address, address, address, address, address, address, address

Telephone: Insert

You can contact the **ASPIRING study team** if you have questions:

Website: www.ASPIRING.ed.ac.uk

Email: Loth.ASPIRING@nhs.scot

Telephone: 0131 537 2944

You can obtain **independent advice** about this study by contacting:

Name: Dr Sarah Keir

Job title: Consultant Physician in Medicine of the Elderly

Address: Western General Hospital, Edinburgh. EH4 2XU

Telephone: 0131 465 9102

The contact for **complaints in your NHS region** is:

Enter text (Address)

Enter text (Address)

Enter text (email and Tel Number)

The contact for **formal complaints** is:

Name: NHS Lothian Patient Experience Team

Address: Mainpoint, 102 Westport, Edinburgh, EH3 9DN

Telephone: 0131 536 3370 (open Mon-Fri, 9am to 2pm)

Email: Loth.Feedback@nhs.scot