

PLINTH

PLATFORM **STUDY** FOR
INTRACEREBRAL **H**AEMORRHAGE



THE UNIVERSITY
of EDINBURGH



Version 2.0, 15 September 2023

We invite you to consider more information about this study

- Thank you for considering the short participant information that was provided about the PLINTH feasibility study.
- This document provides more information about the study.
- It may take you about 15 minutes to read it.
- Do ask if anything is unclear.
- You can find information about how to contact us at the end.
- Please feel free to talk to your nearest relative or friends about this research study if you wish.
- Joining this research study is entirely up to you.
- Your decision will not affect the standard medical care that you receive.

What's happened so far?

- You've already met one of our team of doctors and nurses who specialise in caring for people with stroke due to bleeding in the brain, known as 'intracerebral haemorrhage' or 'brain haemorrhage'.
- We do research that aims to improve care for people with brain haemorrhage.
- You've been given a brief summary and seen a video about this PLINTH feasibility study.



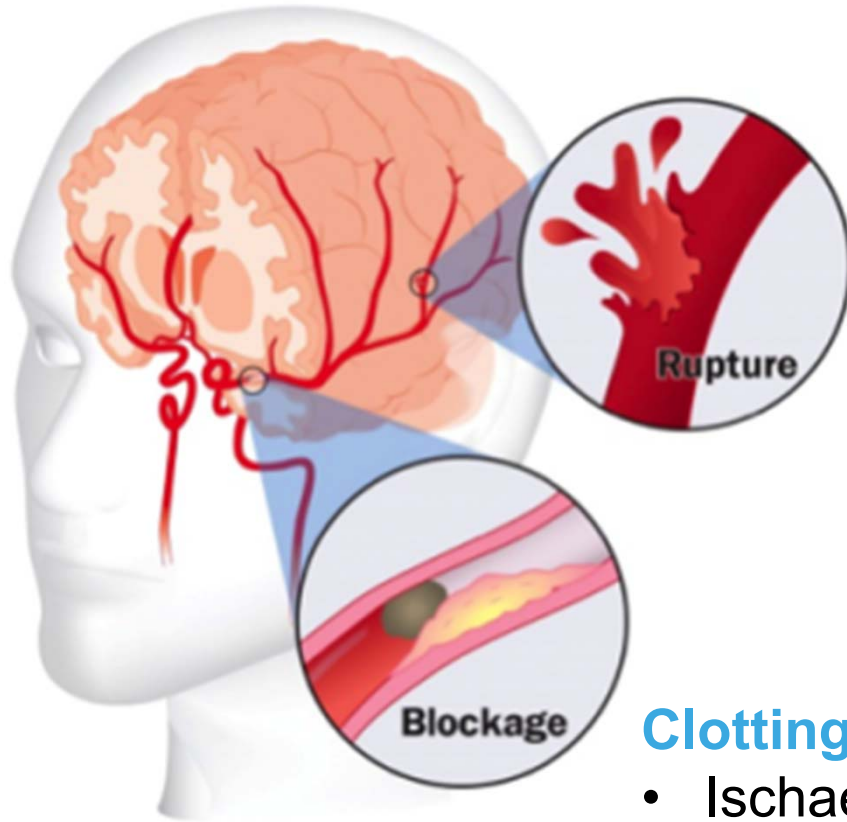
What's next?

- In this presentation, we would like to share some information that is tailored to you about:
 1. Brain haemorrhage
 2. Your care so far and options for your care in future
 3. What's involved in this study, called PLINTH

What's next?

- In this presentation, we would like to share some information that is tailored to you about:
 1. **Brain haemorrhage**
 2. Your care so far and options for your care in future
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There are two types of stroke:



Bleeding, due to blood vessel rupture

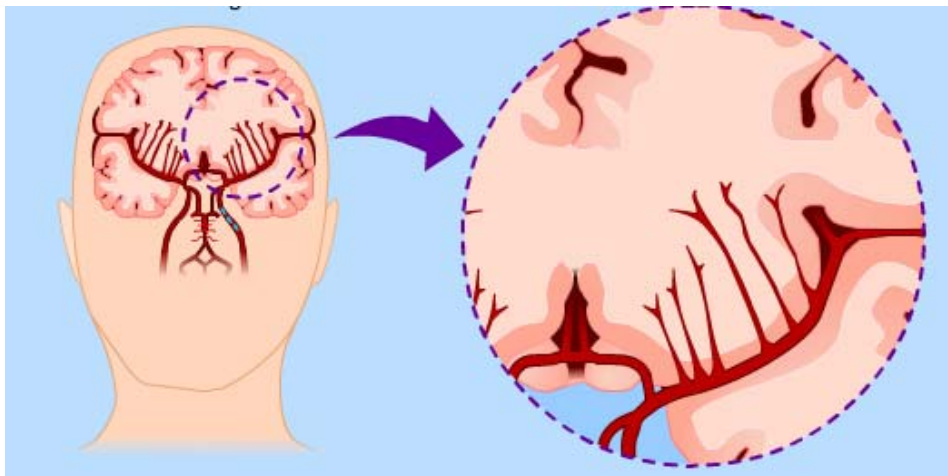
- Haemorrhagic stroke
 - Intracerebral haemorrhage (ICH)
 - Subarachnoid haemorrhage (SAH)

Clotting, due to blood vessel blockage

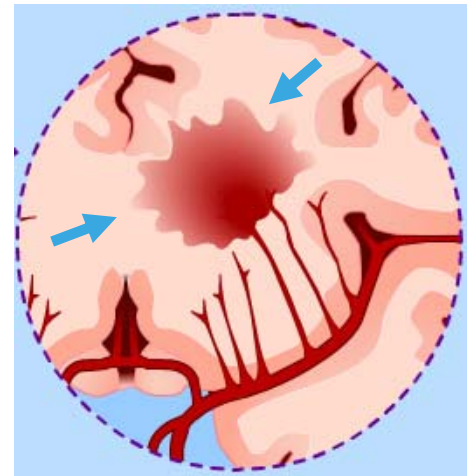
- Ischaemic stroke

You have had a stroke due to intracerebral haemorrhage, known as “brain haemorrhage”

Normal blood vessels



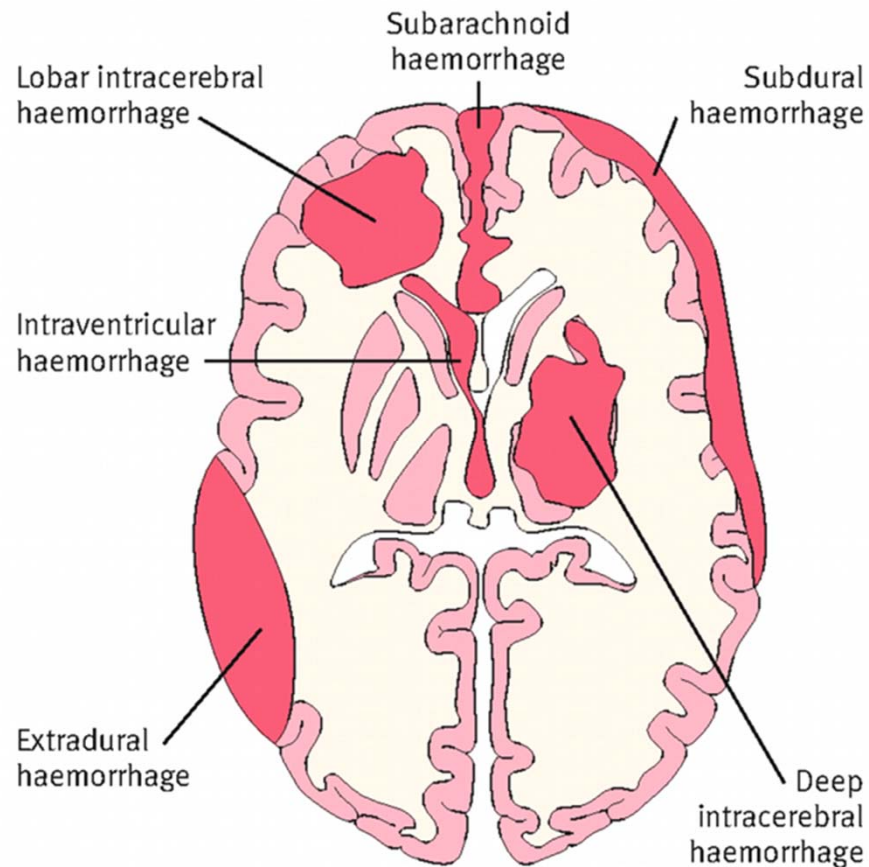
Bleeding in the brain



CT scan: brain haemorrhage

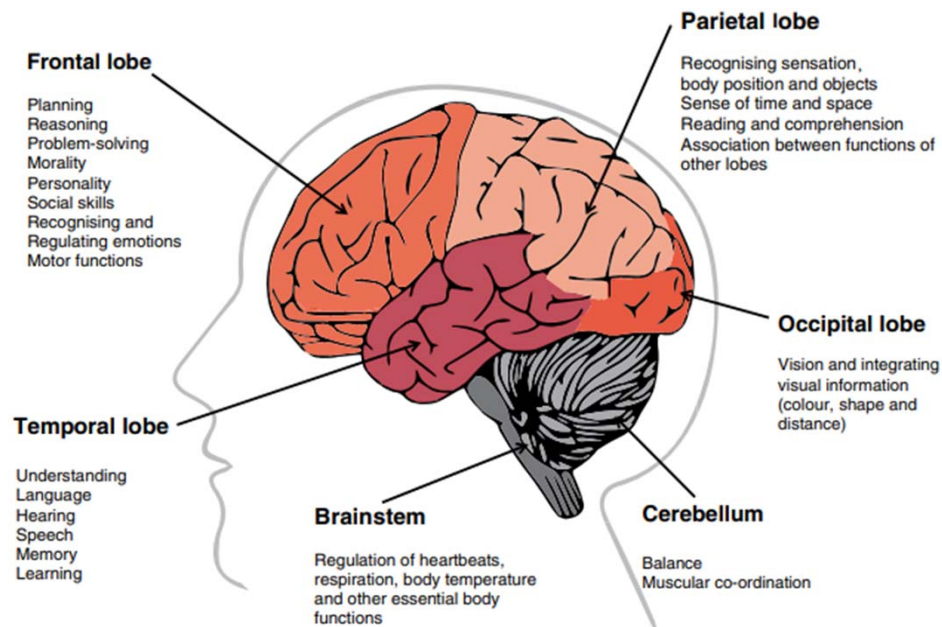


Brain haemorrhage size and spread



- We use your brain scan to measure the amount of blood in millilitres, or “ml”
- Brain haemorrhage can spread to fluid-filled spaces within the skull, such as:
 - Intraventricular
 - Subarachnoid
 - Subdural

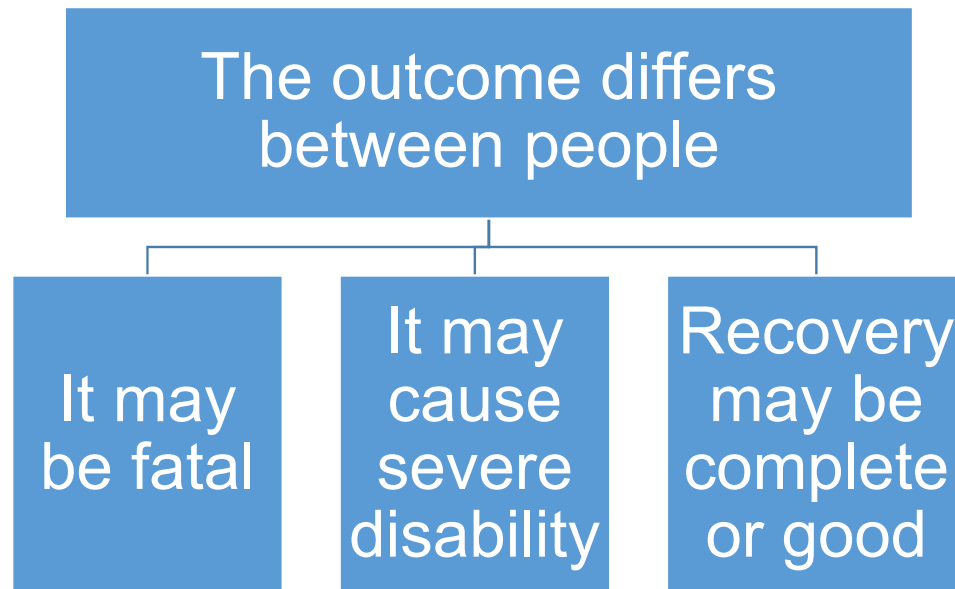
Brain haemorrhage can occur in any part of the brain



Drawing of the lobes and hemispheres of the brain

- The symptoms caused by a bleed depend on the location of the brain haemorrhage

Brain haemorrhage can have serious consequences...



- The outcome depends on the size, location and spread of the bleed
- Currently, we aren't sure which treatments might improve the outcome for people with brain haemorrhage

What's next?

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 - 2. Your care so far and options for your care in future**
 3. What's involved in this study

Now we'll tell you some information about



- Your brain haemorrhage
- Your care so far
- The options for your future care

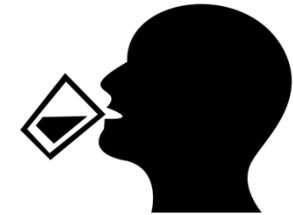
We do things in standard care for brain haemorrhage because they help



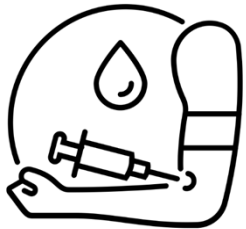
Medical assessment



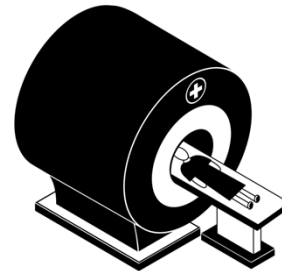
Nursing assessment



Swallow test



Blood tests



Brain scan



Care on a stroke unit

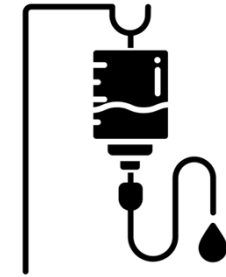
Now we will tell you what your care has involved so far...



Diagnose the cause



Support



Reduce brain injury



Reduce complications



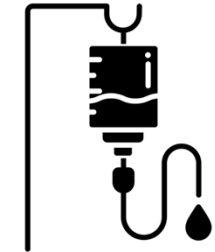
Improve recovery



Prevent another stroke

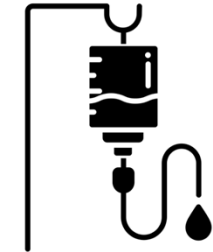
But we don't know if some of the options for care are better than others

- We want to improve recovery after brain haemorrhage by doing more research
- Future research studies might investigate your options



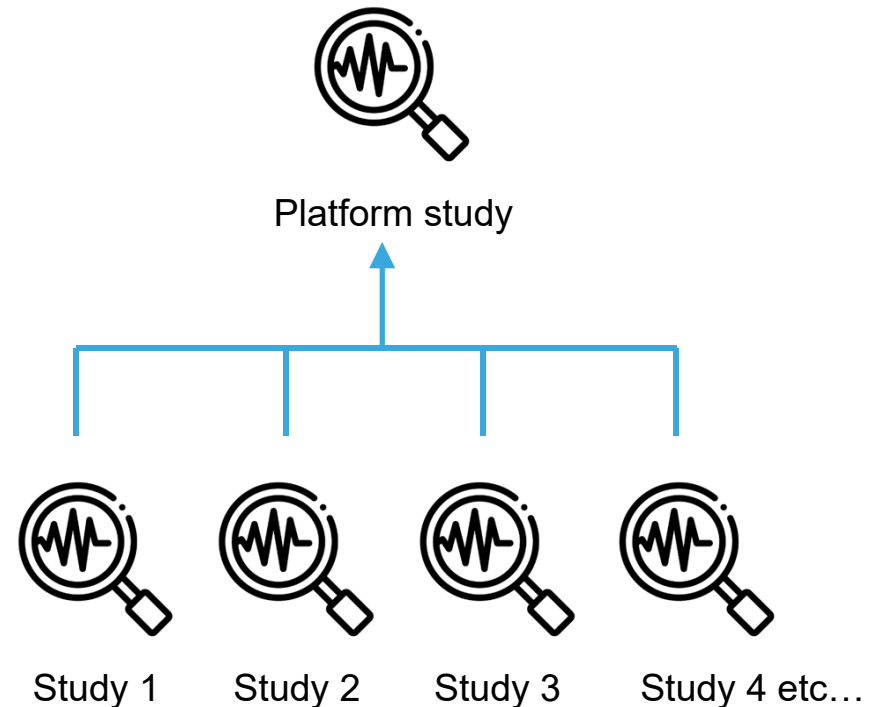
But we don't know if some of the options for care are better than others

- Future research studies might study things that we already do – but only for some people, or in some hospitals – because we're not sure if they work.
- They might also investigate new tests or treatments.



So more research is needed for people with brain haemorrhage

- Many different options may help you and others
- Finding out which option is best improves outcomes for patients
- Usually we investigate each option in separate research studies
- In future we want people with brain haemorrhage to be able to access several options in one study, called a 'platform study'.



Platform study for INTracerebral Haemorrhage = PLINTH, for short

- We are planning a platform study, called PLINTH
- We haven't started PLINTH yet
- First we want to find out whether people would be willing to take part
- We want to find out if PLINTH can be done
- We want to seek your opinion about taking part

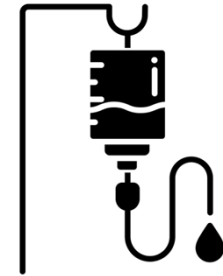
Would a platform study of options for 1 or more aspects of your care be acceptable?



Diagnose the cause



Support



Reduce brain injury



Reduce complications



Improve recovery



Prevent another stroke

What's next?

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What's involved in this study?

- We are doing this study at three hospitals in two regions of Scotland
 - the Royal Infirmary of Edinburgh in Lothian and
 - Monklands and Hairmyres hospitals in Lanarkshire



What's involved in this study?

- We will find people who are first diagnosed with brain haemorrhage between 1 October 2023 and 30 June 2025
- By searching medical records, brain scans, and referrals to stroke services
- During this time, we expect to involve roughly:
 - 170 people in Lothian and
 - 70 people in Lanarkshire

What's involved in this study?

We will include people:

- Who live in Scotland
- Who are aged 18 years or older when diagnosed with brain haemorrhage
- Whose brain haemorrhage is most likely to be caused by small vessel disease in the brain (in other words, age-related wear and tear of the small blood vessels)
- Who survive the brain haemorrhage
- Who have several options for at least one aspect of the future care of their brain haemorrhage

What's involved in this study?

We will not include people:

- Whose hospital doctor thinks it is not appropriate for us to approach about this study

We will ask for consent

- To join the study
 - from the person with brain haemorrhage, or
 - from their nearest relative if the person cannot consent for themselves
- To keep you in the study if you lose mental capacity to make decisions for yourself in future

What would taking part involve?



You have had a stroke due to a brain haemorrhage



Your doctor confirmed that you're eligible for this study



The research team is inviting you to take part. You have time to decide, ask questions and get answers.



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



If you agree to take part, we will:



- Gather some **information from your electronic health records** and keep it confidential.
- Ask you to **sign a consent form**.



There's no obligation to be part of a future study.

What would taking part involve?

If you sign, we'll include you in the PLINTH feasibility study



Interview you or your nearest relative for around 15 minutes, **3 days** after you give consent



Interview you or your nearest relative for around 15 minutes, **14 days** after you give consent



Monitor your electronic health records to see how you get on and keep the information confidential

What would taking part involve?

- You will receive standard care for brain haemorrhage, whether or not you choose to take part.
- In addition to standard care:
 - We've given you **more detailed information** that is tailored to you
 - We'll **gather information** from your medical records
 - We'll **interview** you or your nearest relative twice on **day 3** and **day 14** after you give consent
 - Each interview will last about 15 minutes
 - We'll **monitor your health records confidentially** to see how you get on after you leave hospital

What are the possible benefits of taking part?

- We'll provide you with information about brain haemorrhage so that you may learn more about your health
- You will have the opportunity to ask questions and have them answered by a brain haemorrhage specialist
- We will check how you get on. You may feel supported by this
- We can send you a summary of the results at the end of the study
- The results of this study will help us to design research studies for people with brain haemorrhage in the future

What are the possible disadvantages and risks of taking part?

- There is a low risk that you may find the information about brain haemorrhage distressing. The clinical and research team are experienced and sensitive and they will support you.
- There is an extremely low risk that the confidential information that we hold from your medical records is shared unintentionally, or due to a cyberattack. We use strong security to protect the database storing your information. Research staff have training in information security.
- You may find the time you spend being interviewed inconvenient or tiring. We will go at your own pace and we can talk to your nearest relative instead.

What to expect during the consent process

- We will give you time to consider information about the study.
- You will have the opportunity to ask questions and have them answered.
- You can take as long as you need to decide whether to take part.
- If you want to take part, we will ask you or your nearest relative to sign a consent form.

Informing your general practitioner

- We will ask your clinical team to tell your general practitioner that you are taking part in the PLINTH feasibility study.
- We will not share with them any of the information you provide for the study.

What if something goes wrong?

- If you have a concern about any aspect of this study, please contact the Chief Investigator using the contact details on the last page of this leaflet, who will do his best to answer your questions.
- Alternatively, speak to the independent advisor, whose telephone number is at the end of this leaflet.
- If you remain unhappy and wish to complain formally, you can do this by contacting NHS Lothian Patient Experience Team.
- 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 but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). The contact for complaints in your NHS region is: NHS Lothian Patient Experience Team, Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG. Telephone 0131 536 3770 (9am – 2pm) Email: feedback@nhslothian.scot.nhs.uk. Members of the public in Scotland have their rights and responsibilities set out in the Patients Rights (Scotland) Act 2011

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

- Your decision to take part in the PLINTH feasibility study is entirely voluntary.
- You are free to withdraw from all or part of this study at any time, without giving a reason.
- Any decision to withdraw will not affect the standard medical care that you receive.
- We will ask for your consent to keep and use any information collected about you up to the point of exit from the study should you decide to withdraw.

How will my information be kept confidential?

- PLINTH is run by a team at NHS Lothian and the University of Edinburgh who process your information and take care to protect it.
- The team includes medical, nursing, computing and administrative staff, all of whom have a duty of confidentiality to you.
- Your information will be stored on secure University of Edinburgh servers, in a database that can only be accessed with a valid username and password. 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 research. The University of Edinburgh and NHS Lothian are the data controllers for the study. You have the right to check the accuracy of information held about you and correct any errors. During the study we will collect your contact information (address, telephone, email address) and the contact information of your nearest relative, power of attorney or welfare guardian in order to contact you about the study. We will collect some identifiable data (name, date of birth, CHI Number) to allow us to link to your health records later on. We will also collect medical information from your medical notes in relation to your brain haemorrhage, what treatment you receive for it, and any other conditions or medications you may have. We will access information about how you are getting on from the National Records of Scotland and the Information Services Division of NHS Scotland. We will identify you when we communicate with your GP, to make sure that we are communicating about the correct person. Hospitals involved in PLINTH 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. Sharing data with other researchers is important 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. Therefore, we may share anonymous information from PLINTH with other researchers anywhere in the world, to help answer related research questions. Other countries might not offer the same level of protection of peoples' privacy as that demanded by law in the UK, so we will always ensure that other researchers will not be able to identify you from the information that we share. We do not plan to ask for further ethics committee approval for each re-use of data

What will happen to the results of this study?

- There will be a newsletter about the results which you can choose to have sent to you.
- The results of the study will be submitted for publication in scientific journals.
- We will also make the results available in a format appropriate to the general public on our website.

Who is organising and funding this study?

- The University of Edinburgh and NHS Lothian sponsor the research.
- The Chief Scientist Office of the Scottish Government's Health Department funds the study via a grant paid to The University of Edinburgh.
- Professor Rustom Al-Shahi Salman is the Chief Investigator.



**CHIEF
SCIENTIST
OFFICE**



How have patients and the public been involved in this study?

- Brain haemorrhage survivors were involved in identifying the PLINTH feasibility study as a priority.
- A brain haemorrhage survivor has helped to design the study and was part of the team who applied for funding from the Scottish Government.
- The Research to Understand Stroke due to Haemorrhage (RUSH) patient reference group will monitor the progress of the study.

- You can find information about the RUSH patient reference group here: www.RUSH.ed.ac.uk.



Who has reviewed this 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 insurance required to be in place before the study starts.



What if relevant 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.



What happens when the research stops?

- Anonymised information about you will be kept indefinitely so that researchers can look at it again.
- For regulatory reasons, information about your participation will be archived at your local hospital and at the PLINTH study office for five years.

Who to contact for more information about the study

- **You can contact the PLINTH research team if you have questions:**
- RUSH, Centre for Clinical Brain Sciences, Chancellor's Building, Edinburgh Royal Infirmary, 49 Little France Crescent, Edinburgh. EH16 4SB. Telephone helpline: 0131 537 2944.
- **You can contact your local team about your participation:**
- Professor Rustam Al-Shahi Salman, honorary consultant neurologist. Centre for Clinical Brain Sciences, Chancellor's Building, 49 Little France Crescent, Edinburgh. EH16 4SB. Telephone: 0131 537 2944.
- **You can obtain independent advice about this study by contacting:**
- Dr Sarah Keir, consultant stroke physician. Stroke Unit, Western General Hospital, Crewe Road South, Edinburgh. EH4 2XU. Telephone: 0131 465 9102.

Would you like to take part?