Consultee Information Sheet

Prospective observational study to evaluate the use of Computer aided vacuum thrombectomy within the context of intermediate and high-risk PE.

Introduction

We feel your relative/friend is unable to decide for himself/herself/themselves whether to participate in this research.

To help decide if they should join the study, we'd like to ask your opinion whether or not they would want to be involved. We'd ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide your relative/friend would have no objection to taking part we will ask you to read and sign the consultee declaration on the last page of this information leaflet. We'll then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn.

If you decide that your friend/relative would not wish to take part, it will not affect the standard of care they receive in any way.

If you are unsure about taking the role of consultee you may seek independent advice.

We will understand if you do not want to take on this responsibility.

The following information is the same as would have been provided to your relative/friend.

What is the purpose of the study?

Your relative/friend has a condition called pulmonary embolism (PE), where a blood clot has blocked vessels in your lungs. This can affect breathing, blood flow, and the heart.
In many cases, doctors treat PE with medicines that prevent new clots and allow the body to naturally break them down. (anticoagulation). These are the most common treatment and are given as tablets or injections. But in more serious cases, when the blood clot causes strain on your heart or there's a risk of serious complications, additional treatments may be considered. These may include Clot-busting medicines (thrombolysis) or thrombectomy, a procedure that uses a tube and suction to remove the clot directly from the lung arteries. All of these treatments are already approved and licensed for use in the NHS. The study is not testing a new medicine or procedure.

The TiPE (Thrombectomy in Pulmonary Embolism) study is designed to collect information from patients with moderate to severe PE (what we call "intermediate or high-risk" PE). We are simply trying to collect data on how we use these treatments, and how patients do after treatment. We are not changing your treatment as part of taking part in this study
We will gather data on:

- How patients fare when treated with or without thrombectomy
- The benefits and risks of thrombectomy
- How patients recover over time (symptoms, heart function, quality of life)
- Which clinical or imaging factors predict better or worse outcomes

Our hope is that the knowledge gained will help doctors make better decisions in the future: deciding *who* may benefit most from thrombectomy, and when it is best used, ultimately improving outcomes for future patients with PE.

Why has my relative/friend been invited?

Your friend/relative have been invited to participate in this trial because they have a pulmonary embolism (blood clot). Some may be treated with standard blood thinning medicines, while others may also undergo a procedure called vacuum thrombectomy to physically remove the clot. By collecting information on your treatment, we can assess outcomes and learn who benefits most from each type of treatment.

We plan to include 2000 participants with pulmonary embolisms from 12 hospitals across the UK.

Does my relative/friend have to take part?

No. It is up to you to decide whether or not they would take part. If you decide for your relative/friend to take part, you will be given this information sheet to keep and be asked to sign a decleration form to confirm that you understand what is involved when taking part in this study. Your relative/friend will be given the choice to continue or not with the study, when they are able to do so. If you decide for your relative/friend to take part you are free to withdraw them from the study at any time and without giving a reason. If you withdraw them, unless you object, we will still keep records relating to the treatment given to them, as this is valuable to the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care your relative/friend receives.

What will happen to relative/friend if they take part?

If you agree for your relative/friend to participate in the trial, you will be asked to sign the Declaration Form and be given a copy of this to take away and refer to later.

Step 1: Screening and consent

- We will check their hospital records to confirm they are suitable for the study.
- You will be asked to provide a proxy consent (when they will feel better, we will ask for their consent).

Step 2: Baseline information

We will record details from their medical notes, including their scans, blood tests, symptoms, and medical history.
No extra tests will be done for the study.

Step 3: Your treatment

Their doctors will decide the best treatment for them.

- Some patients will receive standard treatment (blood-thinning medicines, sometimes clot-busting drugs).

- Some patients may also have a thrombectomy procedure to remove the clot. We will record which treatment he/she/they has/have and any side effects or complications.

Step 4: Follow-up
We will follow them up at 1, 3 and 6 months from the procedure, mainly using questionnaires and routine hospital information.

Timepoint	What happens	How long it takes
Baseline (during hospital stay)	Check eligibility, confirm consent, collect details from your scans, blood tests, medical history	No extra time
Treatment (hospital stay)	Record details of your care and any complications	No extra time
1 month	Short questionnaire about your symptoms, wellbeing and recovery (phone, online or by post)	15–20 mins
3 months	Questionnaire; collect results of any scans/tests your doctors have ordered as part of routine care	15–20 mins
6 months	Questionnaire about symptoms and wellbeing	15–20 mins

What will my relative/friend have to do?

If they take part in this study, most of the information will be collected from the hospital records. They will not need to make any extra hospital visits.

The main responsibilities are:

- Questionnaires: They will be asked to complete short questionnaires at 1, 3, and 6 months after his/her/their pulmonary embolism. These ask about the recovery, symptoms, and general wellbeing. They can be completed online, by post, or by phone.
- Telling the medical team if they feel unwell: Your friend/relative will be asked to let the doctor or nurse know if they feel unwell, have unexpected symptoms, or have concerns about the treatment

What are the possible disadvantages and risks of taking part?

Taking part in this study is not expected to expose to risks beyond the usual care for pulmonary embolism, but there are some possible disadvantages:

Extra procedures

- Your friend/relative may be asked to answer some follow-up questions or be contacted by a research nurse to give information on how you are doing
- In some patients an additional Ultrasound scan of the heart will be performed (during your hospital stay), which they may need to lie still for.

Incidental findings

- Occasionally, scans or tests may show up something unexpected (called an incidental finding) that is not related to pulmonary embolism.

- If this happens, the study doctor will discuss the results with your patient /relative and arrange for appropriate follow-up or referral.

Emotional impact

- Being part of a study may sometimes feel stressful or worrying, especially if your friend/relative are asked about your health repeatedly or reminded of their condition.
- The study team is available to support and answer any questions.

What are the possible benefits of taking part?

There is no guarantee that they will benefit from taking part in this trial. However information collected as part of their participation in this trial may benefit patients with Pulmonary Embolism in the future.

What if there is a problem?

Any complaint about the way you or they have been dealt with during the trial or any possible harm they might suffer will be addressed. If you or they have any concerns about any aspect of this trial you or they should speak to your trial doctor who will do their best to answer your/their questions.

In the event that something does go wrong and they are harmed during the research study there are no special compensation arrangements. If they are harmed and this is due to someone's negligence then they may have grounds for a legal action for compensation but they may have to pay their legal costs. The normal National Health Service complaints mechanisms will still be available to tehm.

If you/they wish to complain or have any concerns about any aspect of the way you/they have been approached or treated during this trial, you/they can do this through the NHS complaints procedure. In the first instance it may be helpful to contact the Patient Advice and Liaison Service (PALS) at their hospital.

PALS can be contacted by:
Tel: 01752 439884
Email: plh-tr.PALS@nhs.net

How will we use information about you and your relative/friend?

University Hospitals Plymouth NHS Trust (UHP) is the sponsor for this study and is based in the United Kingdom. We will need to use information from you and your relative/friend, from their medical records for this research project.

This information will include your:
Name and initials

This information will include your relative's/friend's
Name and initials
Date of birth
NHS number
Hospital number
Contact details (address, phone number, email)

People will use this information to do the research or to check their records to make sure that the research is being done properly.

People who do not need to know who they are will not be able to see their name or contact details. Their data will have a code number instead.

UHP is responsible for looking after their information. We will share their information related to this research project with the following types of organisations:

- Dendrite Clinical Systems (UK based company specialising in data)
- University of Plymouth (UK University for statistical support)

We will keep all information about them safe and secure by:

- Storing their data on encrypted, password-protected systems
- Restricting access only to members of the research team and relevant authorised personnel
- Using coded identifiers instead of their name whenever possible
- Regularly auditing data access and storage processes to ensure ongoing compliance
- All data will be collected, processed, and stored in accordance with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.

We may share or provide access to data about them outside the UK for research related purposes to:

- Pulmonary Embolism and/or Computer Assisted Vacuum Thrombectomy

If this happens, we will only share the data that is needed. We will also make sure they can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if they have a rare illness, it may still be possible to identify them. If their data is shared outside the UK, it will be with the following sorts of organisations:

- Penumbra Inc. (USA medical device company with global offices, the Funder)
- Other Health and Academic Institutions that carry out health research

We will make sure their data is protected. Anyone who accesses their data outside the UK must do what we tell them so that their data has a similar level of protection as it does under UK law. We will make sure their data is safe outside the UK by doing the following:

- (some of) the countries their data may 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, for example, member states of the European Union.
- 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: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/

- we do not allow those who access their 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 their data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect their 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 them and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/report-a-breach

How will we use information about your relative/friend after the study ends?
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 they took part in the study.

We will keep their study data for a maximum of 5 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your relative's/friend's information is used?

- You can stop them being part of the study at any time, without giving a reason, but we will keep information about tem that we already have
- If you choose for them to stop taking part in the study, we would like to continue collecting information about their health from central NHS records, their hospital, their GP. If you do not want this to happen, tell us and we will stop
- You have the right to ask us to access, remove, change or delete data we hold about them for the purposes of the study. You can also object to our processing of their data. We might not always be able to do this if it means we cannot use their data to do the research. If so, we will tell you why we cannot do this

Where can you find out more about how your relative's/friend's information is used?
You can find out more about how we use their information, including the specific mechanism used by us when transferring your personal data out of the UK:

- at http://www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team, or
- by visiting https://www.plymouthhospitals.nhs.uk/privacy-notice-for-patients-
- by sending an email to the Sponsor Data Protection Officer: informationgovernancepht@nhs.net

What will happen if you don't want your relative/friend to carry on with the study?
If you decide you do not want them to carry on with the study, you may withdraw them at any time (unless they have given their consent) and without giving a reason (although we may ask you for a reason, to help us design better studies for the future, it is up to you whether you are

happy to supply a reason or not). If you withdraw them, we will still keep records relating to the treatment given to them, as this is valuable to the study and their safety. A decision to withdraw them at any time, or a decision not to take part, will not affect the quality of care they receive.

Will the study information help with other research projects?

It is important that good quality research data can be shared with others in order to advance clinical research and to benefit patients in the future. After the end of the study, de-identified information collected during the study may be made available to other researchers under an appropriate data sharing agreement, but it will not be possible to identify them or their family personally from any information shared.

What will happen to the results of this clinical trial?

The results of the study will be available after it finishes and will usually be published in a medical journal or be presented at a scientific conference. A summary of the results might be posted in the UHP social media or UHP website. The data will be anonymous and none of the patients involved in the trial will be identified in any report or publication.

A copy of the results may be sent to them at the end of the study.

Who is organising and funding this clinical trial?

The trial is being funded by Penumbra, a commercial medical device company.
Penumbra will not be involved in their clinical care, and they will not decide how they are treated. The company may have access to anonymised study data in order to help analyse results, but they will not have access to their name, contact details, or any information that could directly identify them.

This study is being organised by University Hospitals Plymouth NHS Trust in collaboration with research teams across the UK. The study team at their hospital will remain responsible for their care and for ensuring the research is carried out properly.

Who has reviewed the trial?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect their interests. This study has been reviewed and given favourable opinion by the Health Research Authority, the Research Ethics Committee and the Research & Development team at Derriford Hospital.

Further information and contact details

If you have any questions about the study, please speak to their study nurse or doctor, who will be able to provide you with up to date information.

Doctor: <add name>	**Research Nurse:** <add name>
Tel. Number: <add number>	**Tel. Number:** <add number>

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.