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Participant Information Sheet

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

You are being invited to take part in a research study. Before you decide whether or not 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, and discuss it with others if you wish.

Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

You have a condition called pulmonary embolism (PE), where a blood clot has blocked vessels in your lungs. This can affect your breathing, blood flow, and your heart.
In many cases, doctors treat PE with medicines that prevent new clots and allow the body to naturally break them down (anti-coagulation). 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 your 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 have I been invited?

You have been invited to participate in this trial because you have a pulmonary embolism (blood clot). Some of you may be treated with standard blood thinning medicines, while others may also undergo a procedure called vacuum thrombectomy to physically remove the clot.

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By collecting information from you treated with either treatment, we can compare 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.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time and without giving a reason. If you withdraw, we will still keep records relating to the treatment given to you, 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 you receive.

What will happen to me if I take part?

The treatment you will receive is decided by the medical team treating you. The study will not influence the decision and only record the treatment and data about you.

If you agree to participate in the trial, you will be asked to sign the Informed Consent Form and be given a copy of this to take away and refer to later.

Step 1: Screening and consent

- We will check your hospital records to confirm you are suitable for the study.
- You will be asked to give consent (or a relative may give proxy consent if you are too unwell at first; when you will feel better, we will ask for your consent).

Step 2: Baseline information

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

Step 3: Your treatment

Your doctors will decide the best treatment for you.

- 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 you have and any side effects or complications.

Step 4: Follow-up

We will follow you 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 for you

Timepoint	What happens	How long it takes
Treatment (hospital stay)	Record details of your care (standard treatment or thrombectomy) and any complications	No extra time for you
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 do I have to do?

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

Your main responsibilities are:

- Questionnaires: You will be asked to complete short questionnaires at 1, 3, and 6 after your pulmonary embolism. These ask about your recovery, symptoms, and general wellbeing. They can be completed online, by post, or by phone.
- Telling us if you feel unwell: Please let your trial doctor or nurse know if you feel unwell, have unexpected symptoms, or have concerns about your treatment using the contact details at the end of this information sheet.

What are the possible disadvantages and risks of taking part?

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

Extra procedures

- You 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 you may need to lie still for.

Radiation exposure

- Some of the scans used to diagnose and monitor pulmonary embolism involve ionising radiation, such as CT scans. These procedures use ionising radiation to form images of your body to aid diagnosis and treatment. Ionising radiation may cause cancer many years or decades after the exposure. The chances of this happening to you are the same whether you take part in this study or not.

- The amount of radiation you receive from a CT scan of the chest is about the same as you would get from several years of natural background radiation or taking a long-haul flight (e.g. London to New York).
- This exposure is considered low risk, but repeated scans increase the dose.

- An interventional radiology thrombectomy procedure and subsequent follow-up CT scans may be part of your routine care. If you take part in this study you will not undergo any additional imaging procedures. These procedures use ionising radiation to form images of your body to aid diagnosis and treatment. Ionising radiation may cause cancer many years or decades after the exposure. The chances of this happening to you are the same whether you take part in this study or not.
- Your study doctor will ensure you only have scans that are necessary for your care.

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, your study doctor will discuss the results with you and arrange for appropriate follow-up or referral.

Emotional impact

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

What are the possible benefits of taking part?

There is no guarantee that you will benefit from taking part in this trial. You may experience relief in your symptoms. However information collected as part of your 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 have been dealt with during the trial or any possible harm you might suffer will be addressed. If you have any concerns about any aspect of this trial you should speak to your trial doctor who will do their best to answer your questions.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed 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 you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this trial, you 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 your hospital.

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

How will we use information about you?

University Hospitals Plymouth NHS Trust is the sponsor for this study and is based in the United Kingdom. We will need to use information from you, from your medical records and your GP for this research project.

This information will include your:
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 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 instead.

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

- Dendrite Clinical Systems (UK based specialist provider service)
- University of Plymouth (UK University for statistical support)

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

- Storing your data on encrypted, password-protected systems
- Restricting access only to members of the research team and relevant authorised personnel
- Using coded identifiers instead of your 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 you outside the UK for research related purposes:

- 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 you can't 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 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 your data is protected. Anyone who accesses your data outside the UK must do what we tell them 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 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 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 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 you 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 you took part in the study.

We will keep your 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 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, your hospital, your 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 you for the purposes of the study. You can also object to our processing of your data. 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

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

You can find out more about how we use your 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 I don't want to carry on with the study?

If you decide you do not want to carry on with the study you may withdraw at any time 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, we will still keep records relating to the treatment given to you, as this is valuable to the study and your safety. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you 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 you or your 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 you 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 your clinical care, and they will not decide how you are treated. The company may have access to anonymised study data in order to help analyse results, but they will not have access to your name, contact details, or any information that could directly identify you.

This study is being organised by University Hospitals Plymouth NHS Trust in collaboration with research teams across the UK. The study team at your hospital will remain responsible for your 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 your 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 your study nurse or doctor, who will be able to provide you with up to date information.

Doctor: <add name>

Tel. Number: <add number>

Research Nurse: <add name>

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.