

A Research Study: **Reducing blood clots in liver transplantation**



Do you want to take part?

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About this booklet



It will probably take about 10 minutes to read this leaflet.



We want to see if we can improve how we do liver transplants.

Health Research



We want to find this out by doing a health research study.



**Cambridge
University Hospitals**
NHS Foundation Trust



**UNIVERSITY OF
CAMBRIDGE**

**We are health researchers at
Cambridge University Hospitals and
University of Cambridge.**



Blood and Transplant

**We are working with your local
hospital and the NHS Blood and
Transplant Service.**

Would you like to take part in our study?



Now you are on the waiting list for a liver transplant, we would like to invite you to join our research study.



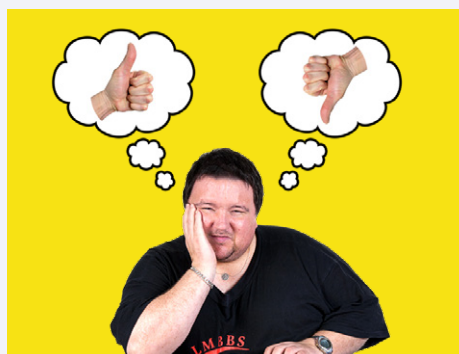
This booklet explains what the study is about.



Someone from the research team at your hospital will go through the booklet with you.



You can go through the leaflet with someone from your family, or with someone who supports you.



Once you are sure you understand what the transplant team would like to do, then you can decide if you want to join our study.



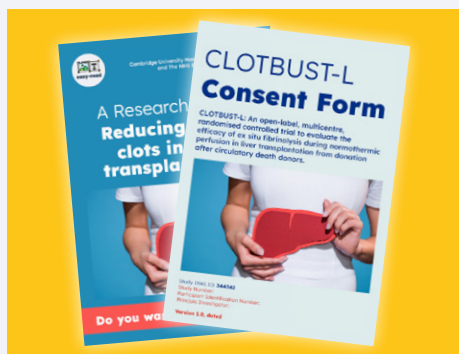
If you would like to join the study, bring this information sheet and the study consent form:



to your next clinic visit with the transplant team



or to hospital if you are called in for a transplant.



Don't worry if you forget the form.

The staff at the hospital will have all the information at the appointment.



Our study is funded by the National Institute for Health and Care research.



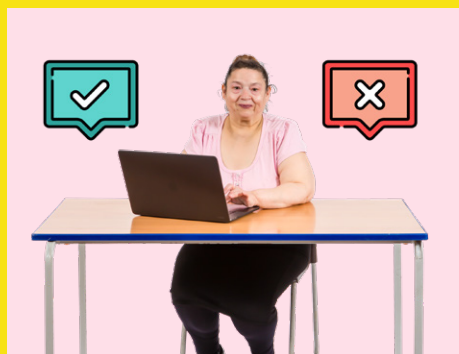
This leaflet uses **Blue Words. When a word or a phrase is difficult, we have written it in **Blue Writing** and explained it in the document.**



Please feel free to ask the research team any questions.



Take your time to decide if you want to join the study.



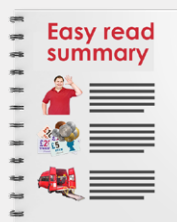
IMPORTANT

You do not have to take part if you do not want to.



The short name for our study is CLOTBUST-L.

It has a longer name which is at the end of the leaflet.



This easy read leaflet has all the information you need to decide if you want to take part.

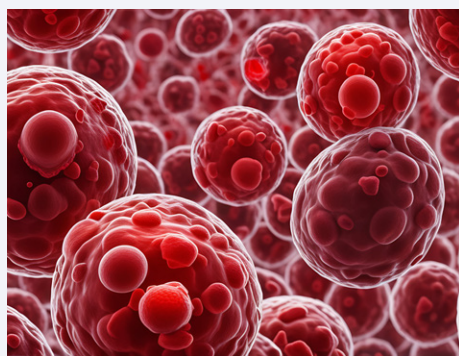


However you can choose to read the longer CLOTBUST-L information leaflet.



Ask the research team if you would like to read this – it will be available to you in both paper format and electronic (PDF) format via email.

About our liver transplant study



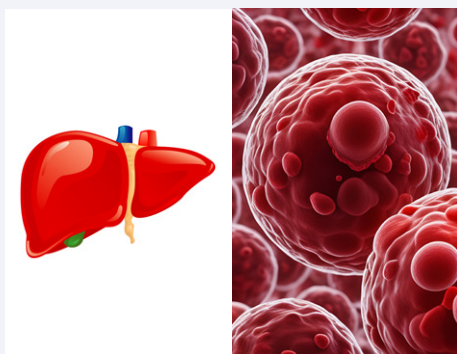
When a liver is ready to transplant, sometimes it contains blood clots.



After the transplant, we believe these blood clots may cause the liver to not work as well as we would like.



But - we are not sure if it is the blood clots which cause the transplanted liver to not work as well as we would like.



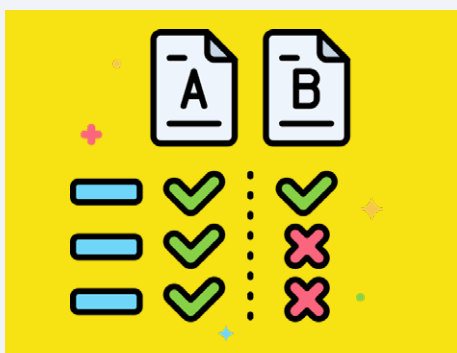
In our study, we shall remove the blood clots from some livers before the transplant.



We will do this by using a common clot dissolving medicine.

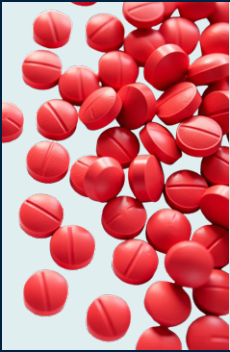


This kind of study is called a **clinical trial.**



****Clinical trials** compare a new medical treatment to the usual care that is already available.**

In our CLOTBUST-L trial:



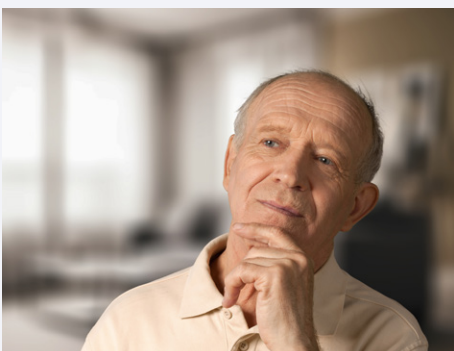
half of the people will have a transplant of a liver which has had the clot dissolving medicine.



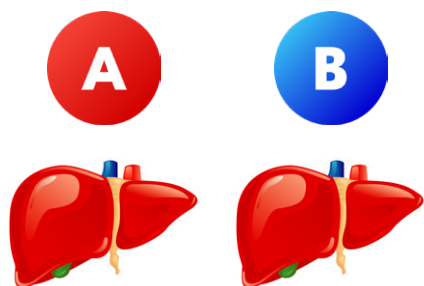
half of the people will have a transplant of a liver which has NOT had the clot dissolving medicine.



Both the surgeon and the study team will know if your new liver has been given the clot thinning medicine or not.



You will have the choice whether to know this too.



We will see if there is a difference between the two liver transplant groups.



We can then see if the clot thinning treatment has made a difference for the better.



If it has, this means we can make future liver transplants more successful.

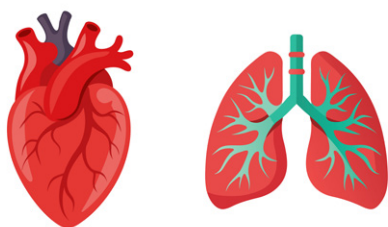


There is another important rule.

The rule is that:



We will only use the clot thinning medicine on livers which have been donated after **circulatory death**.



A donation by **circulatory death** means a person's heart and breathing have stopped and cannot start again.



Some livers are donated once the brain has completely stopped working. This is called **brain death**.



Livers donated after brain death cannot be part of the CLOTBUST-L study.



**This
means...**

This means that you:



may be happy to take part in our study

and

A photograph of a white document with the word 'Consent' at the top. Below the title is a large green checkmark. At the bottom of the document, there is a line for a signature that says 'S Yourname'. A hand is shown signing the document with a black pen. The document is set against a green background.

agree to take part and sign a consent form



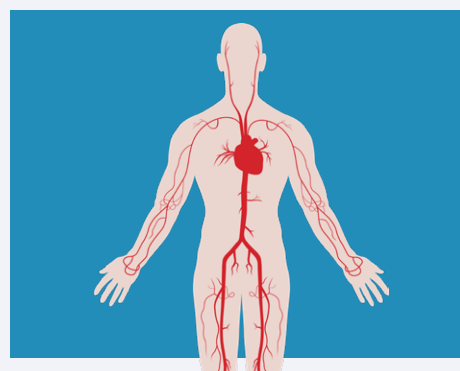
**But you would not join the study as your
donated liver is after a brain death.**



How is the donated liver given the clot dissolving medicine?



The donated liver is placed in a machine, like the one in the photograph.



The machine provides the liver with an artificial blood supply.



The clot dissolving medicine is added to the artificial blood supply provided to the liver on the machine.



The machine is used across the NHS.



Are there any risks to me if I take part in the CLOTBUST-L study?



Using clot dissolving medicine is the only change to the usual way of having a liver transplant.



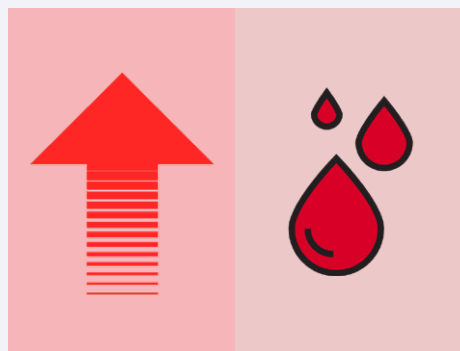
This medicine is regularly used to manage strokes and heart disease.



The research that has been done so far suggests that the treatment is safe and does not cause harm to the liver or to the person receiving the transplant.



It is possible that the treatment will not work as well as the usual way we do a liver transplant.



There is also a chance that there is more bleeding than usual during the transplant operation.



You will not need to take any other special medicine for the study.



There is one extra **biopsy** on the liver.



A **biopsy** means taking a very small piece of the liver to examine it.



This happens after the new liver is put in your body.



Doing a number of **biopsies** during a transplant is normal.



There is always a risk of bleeding or leaking from the liver when doing a biopsy.

Managing risk



We will manage this risk as part of our routine liver transplant work.

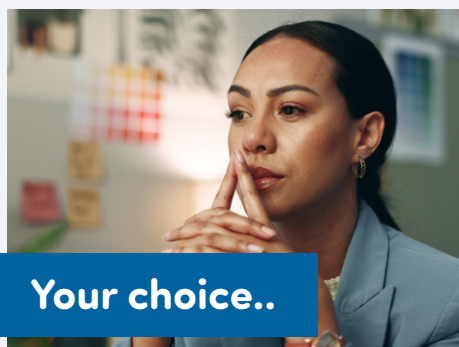


Although we cannot be sure, we do not think there will be any risk to you in taking part.



A member of the research team will contact you if new information changes the safety of the study.

Do I have to take part?



No. Taking part in this study is completely voluntary.



A group of people not connected with the study have checked everything about the study before it can start.

Research Ethics Committee



This group is called a Research Ethics Committee.



This group has health and social care experts as well as ordinary people who have been patients or carers themselves.



Medicines &
Healthcare products
Regulatory Agency

The Medicines and Healthcare Products Regulatory Agency has also approved the study.



People who have had a liver transplant, or who are on the waiting list, have helped with making our study.



Their carers and loved ones have helped as well.



Some of those people will carry on helping us all the way through the study.



If I take part, what will happen to me?



If you agree to take part in the study, you will receive the same clinical care that you would have received if you were not part of the study.

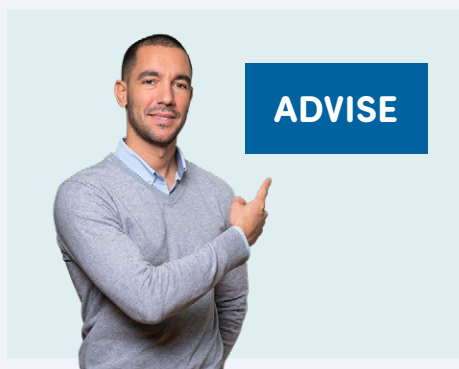


This includes the blood tests and biopsies that normally happen.



You will be asked to identify at least one person who is familiar with your wishes to be involved in the study.

This person(s) is called a **consultee.**



They can advise doctors if you become too unwell around the time of the transplant to decide for yourself whether to take part in the study.



Your consultee(s) could be a family member or friend (personal **consultee) or a doctor (professional **consultee**).**



This can be any doctor who is looking after you but is not involved in the study directly.



You will be treated the same as any other transplant patient.



The only difference will be that your new liver may receive the clot dissolving treatment before the transplant.



Everyone who joins the study will have one extra scan of the liver, if they have not had one already after their transplant.

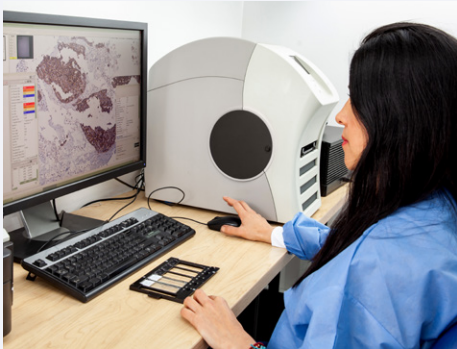


This happens 6 months after the transplant.

A lot of the time this scan happens anyway.



This extra scan will tell us about changes to the way the new liver is working.



It is this extra scan that tells us if the blood dissolving treatment improves the transplant success.



The extra scan is usually at the transplant centre.

It is called a MRCP scan.



We may be able to find a hospital closer to home where the scan can take place.



Once you have had this scan and your 6-month blood tests, your part in the study will come to an end.



Being happy to take part



Everyone needs to be happy that they understand the study.



You will be asked to sign a consent form.



Signing the consent form means that you understand what the study is doing and that you agree to take part.



This means saying yes or no to the questions on the consent form.



Once you have signed the consent form, your part in the study can start.



There is no payment for taking part in the study.



If your extra scan is for research purposes, we will pay for any travel expenses you have when you come to the hospital.

Other information



We will keep a record of the information about your health and treatment during the study.



The information collected about you is kept very safe on our NHS secure computers.



Importantly, the research makes information about you anonymous.

ID number



This means your personal details are removed and you are given a study ID number.



This means that you cannot be identified by anyone looking at the study results.



We may share your anonymous study information with:



the company who makes the machine we use for the clot dissolving.



organisations who check that research is done properly



other researchers across the world to support further research



Sometimes it is not possible to keep your information anonymous. For example, if you have a rare disease.



We will keep your study information for 15 years.



STOP

You can stop being part of the study at any time, without giving a reason.



However, we will keep information about you that we have already collected.



We will also collect information about your health from your hospital records and the UK Transplant Registry.



No thank you

If you do not want this to happen, tell us and we will stop.



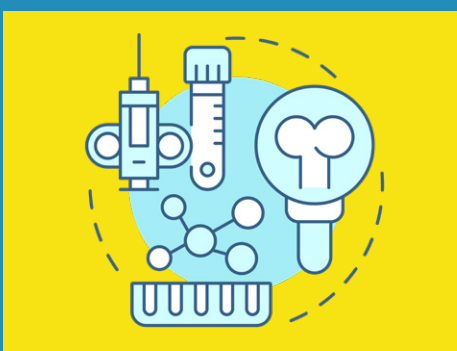
You can also agree to be contacted about participating in future research.



The research team at your hospital will contact you regarding the results of the study.



Because we need enough people to take part, it may be over 4 years before you hear from us.



Cambridge University Hospitals Biobank



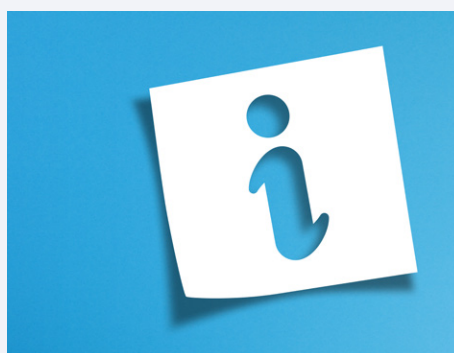
We will ask you to agree for your liver biopsy samples to be stored in the Cambridge University Hospitals Biobank.



A Biobank is where people have agreed that their samples can be frozen and safely stored.



These samples can be then used for future research in the UK and abroad.



You can find out more about how we use the study information collected:



by going online:

www.hra.nhs.uk/patientdataandresearch



by asking one of the research team

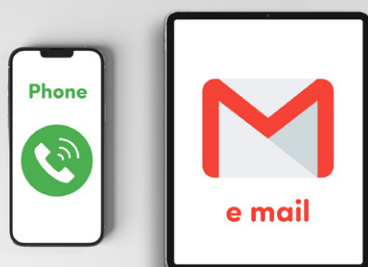


by sending an email to Mr Kosmoliaptsis:

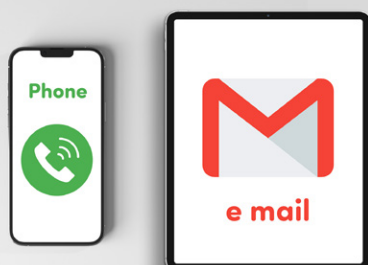
v.kosmoliaptsis@nhs.net



Complaints



For any issues, please contact the team on telephone number or via email on:



You can also contact the NHS Patient Advice and Liaison Service (PALS) on:



This booklet calls the study CLOTBUST-L.



The official name for the study is:

An open-label, multicentre, randomised controlled trial to evaluate the efficacy of ex situ fibrinolysis during normothermic perfusion in liver transplantation from donation after circulatory death donors.



Thank you for thinking about taking part in this study.



If you decide to take part, we will ask you to sign the consent form.



You will need to sign the consent form which is attached to the relevant Patient Information booklet for you.



One of the research team can support you with any questions you may have about the consent form.



This document has been co-produced with:

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Elise Martin-De-La-Torre, Steven Largent, Stuart Tredree,
Becca Jackaman, Simone Meyer and Grace Hill.**



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Online:
thinklusive.org



e-mail:
hello@thinklusive.org



LinkedIn



Made by
Thinklusive