PARTICIPANT INFORMATION SHEET

The PLUG Study

A feasibility study investigating the Prevention of post-operative gastro-oesophageal anastomotic Leaks with the Use of a surgical adhesive, BioGlue

Version 2.0 20/01/2020

You are invited to take part in a research study. Your participation is entirely voluntary. This information sheet will explain what the research study is and why it is being carried out. Please take this information sheet away with you, read it and discuss it with others if you wish. Please ask the study team any questions you may have.

What is the purpose of the study?

This research study will investigate whether a type of surgical glue can be used for patients having surgery for cancer of the oesophagus (gullet). A risk of this sort of surgery is a leak from the join between the stomach and the oesophagus. If this occurs, it means people need to stay in hospital for treatment and can mean they become seriously unwell. This study is the first step to find out if a type of surgical glue can help reduce the number of patients who suffer a leak.

This study will assess how easy it is to use and make sure it is safe to use in this way. We hope that this study will allow us to take on a much bigger study to look further into the potential benefits of this technique.

What will happen if I take part?

If you decide to take part in the study, the surgeon will apply the glue on top of the join they make between your stomach and oesophagus. It is important to understand that the glue will be applied in addition to (not instead of) the normal way of making the join. The application of the glue to the join will be video recorded and kept for study records. This is done using the key-hole camera that the surgeons use to do the operation inside the body. You will not be identifiable from this recording and it will only be used for internal study purposes. Other than adding the glue during your operation, your care will otherwise be identical to if you were not part of the study. If you decide not to take part in the study, you will receive the normal high-quality care from your surgeon and the wider team in the hospital.

This study will look at how feasible it is to carry out a large-scale study, in many different hospitals.

Why have I been invited to participate?

We are inviting all patients who will have surgery for cancer of the oesophagus to take part in our study.

What if I change my mind?

Participation in the study is voluntary. You may decide to not take part at any time without having to give a reason (although understanding people's decisions allows us to make changes and improve our service if we can). If you choose to withdraw from the study after your operation then the

information we have collected on your operation and recovery up until the point of withdrawal will be used in the analysis of the results. Please be aware that once the glue is in place it cannot be removed.

What are the possible benefits of taking part?

We believe that by using this glue in addition to the normal way of making the join, we may reduce the number of people who have a leak from the join between their stomach and oesophagus. We will use the information we get from this study to help plan a larger scale study in the future. At this point we do not know for certain if using the glue will cause a lower leak rate, a higher leak rate or have any effect on the leak rate at all. This study will help surgeons and patients decide whether the use of this glue is better or not.

What are the possible risks or disadvantages of using the glue?

The glue we are using has been used for many years in different areas of surgery (mainly surgery on the heart and blood vessels). We do not expect there to be any significant increased risk from the use of the glue, but there are some small risks from the glue:

- Inflammation directly as a result of the glue
- Allergy to the glue's ingredients
- Damage to the normal tissues around the join
- Possible transmission of infection from material of animal origin

The glue has been used since 1998 and is regulated and licensed for use in the alimentary tract (gut).

How will I be monitored?

You will be monitored closely, as is normal for anyone having this operation. Your follow-up appointments will not be changed by being part of the study. Six weeks after your surgery you will be asked to come for a review with the research team. This is in addition to your normal follow up checks at the hospital. We will collect standard information about how you are and if you suffer any complications, as we would for any patient.

What if something goes wrong?

If anything were to go wrong during or after your operation you would be managed as is normal for all patients after they have had an oesophagectomy. As your surgeon will have explained to you, this is a major operation and it does have risks associated with it. All of the surgeons who perform this operation are experienced consultants and take a very active role in the close management of their patients during their entire journey.

We do not expect any complications related to the use of the BioGlue but if there were to be one, your care would again be coordinated by your surgeon and their team and they would take all appropriate steps to help your recovery, which if you were at home would mean admission to hospital. Once the glue is in place, it is very difficult to remove and we would only attempt to do this in the most extreme circumstances. From the glue's use in many other areas of surgery we have evidence to show there is an adequate margin of safety with this product.

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal Portsmouth Hospital NHS Trust local complaints services are available to you:

Patient Advice and Liaison Service (PALS), A-level Atrium, Queen Alexandra Hospital	
Telephone	02392 286309
Email	PHT.PALS@porthosp.nhs.uk

The sponsor, Portsmouth Hospital NHS Trust, holds insurance policies which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you have any concerns about any aspect of the way you have been treated during the course of this study, then you should immediately inform the Investigator (Mr Nick Carter, Telephone: [Insert]), who will address this for you.

What if new information arises during the course of the study?

If new information (for example relevant changes in details on the safety of BioGlue) arises during the study you will receive written communication from the chief investigator in a timely manner.

Who has reviewed this study?

The South-Central Berkshire B Research Ethics Committee, which has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from the Sponsor, Portsmouth Hospitals NHS Trust and NHS England, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

What happens to the data when the research study ends?

When the study is finished, we plan to tell patients the results by letter, email, social media or publication. The results from this study will be presented at surgical conferences and published in a surgical journal to disseminate the findings. No names of patients will ever be used in any of these materials.

The results will also inform us as to whether it is worth proceeding to a larger multi-centre study or not, and if we do, to use any lessons learnt from this study to improve the design of the larger study. We hope this will add important knowledge to the techniques used for oesophageal cancer surgery.

In line with the Good Clinical Practice guidelines, at the end of your study, your data will be securely stored for a maximum of 15 years after which it will be destroyed.

How will we use information about you?

We will need to use information from you and your medical records for this research project. This information will include your name, NHS number and contact details held by the site and the sponsor for the research. 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. We will keep all information about safe and secure.

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. We need to manage your records in a specific way for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients or by asking the research team or calling 02392 286000 and asking to speak to Emile Armour, Information Governance Manager.

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-for-all-sponsors/

What if I do have any questions?

You can contact us during working hours by ringing or emailing the surgical research team on 02392 286000 ext 3052 / Maria.Moon@porthosp.nhs.uk

Local Study Contact Details:
CI/PI: Mr Nicholas Carter, Consultant Surgeon
Sub-investigator: Mr Alexander Darbyshire
Research Nurse: Maria Moon
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