**REDUCe STUDY**

**REpeated Drainage in Untreatable Cirrhosis**

**Palliative Long-term Abdominal Drains**

**versus**

**Repeated Drainage for Ascites due to Cirrhosis**

**PATIENT INFORMATION SHEET**

**REC ref no: 15/SC/0257**

We would like to invite you to take part in a research study. Before you decide whether you would like to take part, it is important you understand what the research is about. Please read this information sheet carefully.

Please feel free to ask us if there is anything that is not clear or if you would like more information.

**1. Why have I been invited?**

You have a liver condition called cirrhosis that has been complicated with untreatable fluid in the stomach (ascites). A liver transplant is not possible.

**2. What is the purpose of the research study?**

The purpose of this study is to assess a new method to treat untreatable ascites in individuals with advanced cirrhosis.

The usual care of untreatable ascites involves placing a tube called a drain through the skin of the stomach under local anaesthetic. The drain stays in for 4-6 hours and the fluid is collected in a bag connected to the drain. About 10-15 pints can be drained at a time. The fluid quickly builds up again. This means that people with advanced cirrhosis have to come to hospital every one to two weeks to have the ascites drained. Every time this is done there are risks like bleeding, pain and infection.

When ascites is caused by certain other palliative conditions, it is possible to put a drain in the stomach that stays there permanently. This is called a long-term drain (see photograph below). When the fluid builds up, a bag is connected the drain to remove the ascites. 2-4 pints can be removed several times a week as needed. District nurses (and family members if trained) can do this safely, so patients do not have to come to hospital.

Until now, long-term drains have not been used in patients with cirrhosis. This study has been designed to help us understand if long –term drains are better than standard of care in individuals with cirrhosis. This will determine if we need to run a larger study

**3. Do I have to take part?**

No, your participation is voluntary. You can also withdraw from the study at any time without giving a reason. Refusal to participate will not affect your future routine medical care.

If you decide to participate in this study, we will ask you to let us know who you would like us to contact in the event of you losing capacity during the study. This person is called your consultee. If you lose capacity during the study, we would approach your consultee and ask them to act in your best interests to decide whether you continue with the study. If they don’t think it is in your best interests to continue, then we would keep the data we have collected so far but not collect any further data from you.

If you do not have a consultee we will ask your doctor at the hospital, who is not part of the research team, to act in your best interests and decide whether you should continue in the study.

**4. What will happen to me if I take part?**

You will be seen by the Research Doctor or Nurse. They will answer any questions or concerns you may have. When you have had time to read this leaflet the Research Doctor will meet you again or contact you via phone. If you agree to participate you will be asked to sign a consent form. If you are willing, we will also give your contact phone number to an interview researcher to talk to you later about your experience of ascites draining in more detail. You do not have to agree to this, but it will help us understand more about your views. A separate information sheet and consent form will be provided for this.

Then:

1. The Research Doctor will ask some brief questions about your liver condition, and examine you, after which you will undergo routine clinical tests. Around 4 teaspoons (20ml) of blood will be taken as well as taking a small sample of ascitic fluid (around 4 teaspoons, 20ml) to ensure there is no infection present. If infection is found, you will be given antibiotic treatment for five days. We will proceed with the study once this infection has resolved. You may also need an ultrasound if one has not been done recently.
2. Once we know it is safe for you to take part, another visit will be arranged.
3. At this next visit (or just before), a computer programme will be used to randomise (like flipping a coin) participants into two groups: routine clinical care and long-term drain. There will be an equal chance of being allocated to either group but neither you nor your doctor will be able to choose which treatment you have. About four teaspoons (20ml) of blood will also be taken for research purposes (see point 14 below).

You will be asked to complete five questionnaires (you will be shown these before you sign the consent form so you know what they look like). These questionnaires will assess your symptoms, quality of life and use of health services and social care professionals (e.g. GP, hospital appointments, district nurses). These will take under an hour to complete. If you wish the Research Doctor or nurse can help you to complete the questionnaires. Additionally they can also be completed with your carer/people you live with.

*[If you are going to have a long term drain put in, you will be referred to the Royal Sussex County Hospital in Brighton for this. The research doctor and nurse will discuss with you what options you have for travelling to and from the hospital for this one visit. You will be reimbursed for petrol and parking costs if a friend or relative can drive you].* ***Section to be deleted for BSUH and Worthing sites****.*

Depending on which group you are in, slightly different things will occur.

**If you are in Group 1 Intervention (long-term drain):**

1. At the visit for drain insertion, the Research Doctor will ask some brief questions about your health, and your alcohol and drug use, your liver condition, and examine you, after which you will undergo routine clinical tests,. This will include taking a small sample of blood (about 4 teaspoons).
2. The Research Doctor, initially under supervision of a Consultant, will insert the long-term drain into you in a side room in the hospital. This will be done using local anaesthetic and ultrasound to ensure that it is put in the best site for you with minimal pain and discomfort. The Research Doctor will explain to you how to look after your drain. As part of routine care, you will receive an antibiotic, one tablet a day, to reduce the risk of infection in the ascites. You can go home later that day and you will be to continue with your usual daily activities.
3. The Research Doctor will arrange for you to have support at home, from a community nurse to drain fluid through the drain when needed. This will be 2-3 times a week and takes around 30 minutes for each visit. Around 2-4 pints may be drained at a time and will be painless. Bags to drain the fluid into will be provided to you. Your carer, if they wish, can take over draining the ascites instead of the community nurse. They will need basic training from the Research Doctor and community nurses first. Whenever your ascites is drained, this needs to be written down in a booklet you will be provided with and the Research Doctor/nurse will collect this information from you regularly.
4. The Research Doctor/nurse will visit you every two weeks at home for up to 12 weeks. Before each visit s/he will call you to confirm the date and time. Each visit will take up to one hour. They will take about four teaspoons (20 ml) of blood for routine clinical testing and collect the information about amount of ascites drained and if there are any concerns about the drain. They will ask your help in filling in the same three to five questionnaires again at each visit. If you wish the Research Doctor or nurse can help you to complete the questionnaires. Additionally, if you are too unwell, they can also be completed by your carer. If you find it easier, the questionnaires can be answered over the phone within three days of the visit, just let the research doctor/nurse know.

**If you are in Group 2 Routine Clinical Care (drain in hospital when needed);**

1. You will continue to receive current routine clinical care involving hospital visits to drain your ascites and routine bloods every 7-14 days, or depending on your symptoms. Your GP can telephone the hospital to arrange this, or you will be able to come yourself. You will receive an antibiotic, one tablet once a day, to reduce risk of infection in the ascitic fluid. The research doctor will collect information about the amount of fluid drained.
2. The Research Doctor/nurse will visit you every two weeks at home for up to 12 weeks. Before each visit they will call you to confirm the date and time. Each visit will take up to one hour. They will take about four teaspoons (20 ml) of blood for routine clinical testing and will ask your help in filling in the same three to five questionnaires again at each visit. If you wish, the Research Doctor or nurse can help you to complete the questionnaires. Additionally, if you are too unwell, they can also be completed by your carer. If you find it easier, the questionnaires can be answered over the phone within three days of the doctor visit, just let the research doctor know. If the questionnaire assessments coincide with your hospital visits, you can complete them in hospital.

**5. What are the side effects, risks and implications of taking part in the study?**

Participating in the study requires you to spend time every two weeks with the Research Doctor/nurse for up to 12 weeks either face to face and/or over the phone. It is possible that talking about your health may raise topics that you find upsetting or difficult. Please let us know if this happens so we can provide additional support and advice. The researchers will be well experienced in dealing with such situations. For any out of hours emergency we encourage you to contact your GP who will arrange hospitalisation if needed or to go straight to your nearest A&E department. If you decide to withdraw from the study, and wish for the long-term drain to be removed this can be done under local anaesthetic.

**Particular risks for Group 1 Intervention (the permanent long-term drain group):**

The long-term drains have been extensively used in ascites due to other palliative conditions. They are considered safe. But, as with any drain that remains in the body, potential complications could occur such as:

* Pain
* Inability to put the drain in
* Leaking of fluid from the drain
* Bleeding
* Drain blockage
* Infection of the skin where the drain is
* Infection of the ascites fluid (peritonitis)

The risks of these complications are low (fewer than 4 in 100 people will experience these complications). Since you will receive antibiotics during the study, the risk of infection, specifically peritonitis is likely to be even lower.

Experienced doctors will put in the drains using local anaesthetic and ultrasound to ensure that the drain is inserted in the best site for you with minimal pain and discomfort. You will also be closely monitored by the community nursing teams and the Research Doctor/nurse during home visits, so if any complications do occur, they will be promptly identified and acted upon.

Since this is only preliminary work, it is very unlikely that the research blood results will have any significant implications for you. In the unlikely event that they do, this will be discussed both with you and your GP.

**6. What are the possible benefits of taking part?**

There is no guarantee that you will benefit directly from taking part in this research study. Information collected about you and others taking part in this study will help us work out if a much larger study should be done.

If additional information about the problems your cirrhosis is giving you is highlighted in the questionnaires, this could also be directly helpful in your treatment and support. We would encourage you to allow us to tell others involved in your treatment to help tailor your care.

**7. What happens when the research study stops?**

After 12 weeks the study will end and you will continue to receive routine clinical care by your usual hospital consultant and GP. If you have a permanent long-term drain you will have the option to either carry on using it, or have it removed. If you elect to continue using the drains you will be closely monitored by your hospital consultant.

**8. What if there is a problem?**

Any concern about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Advice on how to raise a concern or complaint is detailed below in section 12.

**9. Will my taking part in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. All information that is collected about you during the study will be kept strictly confidential and will be stored in a secure manner compliant with the Data Protection Act. When you join the study, a unique study number will be used to identify your information for the study rather than your name and address being used.

Your medical notes may be seen by authorised individuals from the REDUCe research team, Brighton and Sussex University Hospital Trust, the Brighton and Sussex Clinical Trials Unit, and regulatory authorities or from your local care teams so that they can collect information needed for the research study, and also to check that it is correct.

However, if you tell us about serious risk of harm to yourself or others we will need to break confidentiality, which means letting your GP know.

**10.** **What if relevant new information becomes available?**

Sometimes during the course of a research project, new information becomes available about the equipment being studied. If this happens, your Research Doctor/nurse will tell you about it and discuss whether you want to, or should, continue in the study. If you decide not to carry on, your Research Doctor/nurse will make arrangements for your standard care to continue. If you decide to continue in the study, you will be given an updated patient information sheet to read and asked to sign an updated consent form.

**11. What will happen if I don’t want to carry on with the study?**

Should you wish, you can withdraw from the study at **any** time, without giving a reason and without this affecting your future routine clinical care. If you have been fitted with a long-term drain you can choose to keep this in; otherwise, if you prefer, you can have it removed under local anaesthetic. In this case you will go back to attending hospital every one-two weeks, or as necessary, to have the ascites drained, under local anaesthetic.

**12. Complaints**

If you have a concern about any aspect of this study, you should ask to speak with the research doctor or nurse at your local hospital. The hospital Patient Advice and Liaison Service (PALS) - xxxxxxx can be contacted if you remain unhappy. If you wish to complain formally, you can do this through the NHS Complaints Procedure. Details of this can be obtained from the PALS team.

**13. Will my GP be informed?**

With your agreement, we will inform your GP if you decide to take part in this study.

**14. What will happen to any samples I give?**

All routine blood samples you give will be used at the time and the reason for the test explained. Research blood samples will be labelled with your study number and no other identifiers will be used. They will be stored and tested later in future ethically approved research, for proteins and chemical associated with advanced cirrhosis and in addition may also include genetic testing. At the end of the study all research blood samples will be destroyed in accordance with the hospital procedures.

**15. What will happen to the results of the research study?**

The results of the research study will be written up and published in a scientific journal and discussed at medical conferences. Your personal information will not be identifiable in any way. If you/your carer would like to be sent or emailed a copy, please give us your contact details.

**16. Who is organising the research?**

Brighton and Sussex University Hospital Trust is the sponsor of the research. The research is being organised by a leading liver disease specialist at Brighton and Sussex University Hospital NHS Trust and Brighton & Sussex Medical School as well as collaboration with other hospitals, community trusts and palliative care services in Sussex. Your doctor will not receive any personal financial payment if you take part.

The study is being funded by a Research for Patient Benefit grant from the Department of Health.

**17. Who has reviewed the study?**

To protect your interests, all research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed and approved by the Hampshire A NRES Committee South Central

**18. Contact for further information**

If you or your relatives have any questions or concerns about the study, now or in the future, please call:

*Please insert principal investigator and research fellow details here:*

*Principal Investigator*

*Name:*

*Address:*

*Telephone:*

*Email:*

*Research Fellow*

*Name: Dr Lucia Macken*

*Address: Clinical Investigation and Research Unit (CIRU)*

*Level 10, The Royal Alexander Hospital, (part of The Royal Sussex County Hospital)*

*Eastern Road*

*Brighton*

*BN2 5BE*

*Telephone: via CIRU reception, direct dial 01273 664437 or via hospital switchboard on 01273 696955 ext. 3522*

*Research Nurse*

*Address:*

*Telephone:*

**Thank you for taking the time to read this information sheet and for considering taking part in this research study**

**Consent Form**

**REDUCe Study**

**Consent Form Main Study**

**REC Ref no: 15/SC/0257**

|  |  |
| --- | --- |
|  | **Please initial box** |
| I confirm that I have read and understand the information sheet version \_\_\_\_ for the above study-dated \_\_/\_\_\_/\_\_\_\_. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily  |    |
| I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affectedI understand that relevant sections of my notes and data collected during the study may be looked at by individuals from the REDUCe research team, Brighton and Sussex University Hospital Trust, the Brighton and Sussex Clinical Trials Unit, regulatory authorities or from your local NHS trusts, where it is relevant to my taking part in this research. I give permission to these individuals to have access to my records |        |
| I consent to giving four teaspoons of blood (20 ml) for future ethically approved research. I understand that the blood will be stored in an anonymised manner. I understand that analysis of my blood samples may include genetic analysis. |    |
| I agree to my GP being informed of my involvement in this study  |     |
| I agree to take part in this study  |   |
|  |  |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Patient Date Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person Receiving Date Signature

Consent

**Nominating a Consultee**

I understand that during the course of this study it may become necessary for the research team to contact someone to represent my best interests (known as a consultee). In my opinion I would nominate the following as the person best able to do this:

Name:…………………………………………………

Relationship to participant: …………………………

*(This individual would normally be a ‘personal consultee’ i.e. next of kin, closest relative or friend. If the nominated individual is NOT a ‘personal consultee’ but a ‘nominated consultee’ i.e. a paid carer, please provide information where possible to explain this choice.)*

……………………………………………………………………………………………..

……………………………………………………………………………………………..

Address of Consultee:………………………………………………………

………………………………………………………………….

Contact number of Consultee: ………………………………………………