Palliative Long-term Abdominal Drains Versus REpeated Drainage in Untreatable Ascites Due To Advanced Cirrhosis: A Randomised Controlled Trial (REDUCe 2 Study)

CAREGIVER INFORMATION SHEET

You are being invited take part in a research study that is being run by University of Sussex. Please take time to read the following information carefully and discuss it with others if you wish. Before you decide whether to take part, it is important for you to understand why the project is being done and what it will involve. Please ask if there is anything that is unclear, or if you would like more information. Take time to decide whether you wish to take part.

1. Why have I been invited?

You have been invited because you are a caregiver for someone who has advanced cirrhosis (scarring of the liver) and they are participating in the REDUCe 2 study.

Patients in the REDUCe 2 study are allocated one of two groups to receive treatment for fluid accumulation in the abdomen (ascites).

Group 1 receives the new method of care for cirrhosis patients called a long-term abdominal drain (LTAD) (home drain). This allows community nurses and caregivers (if willing) to drain the patient's ascites at home rather than having to come to hospital. LTADs are used to treat patients with ascites due to other palliative conditions but are currently not standard of care in cirrhosis.

Group 2 receives routine clinical care. This involves repeated visits to the hospital to drain the ascites (called hospital drain).

2. What is the purpose of the research study?

The purpose of this study is to assess the impact on caregivers who care for someone with advanced cirrhosis and ascites. We will assess this by asking you to fill in a questionnaire at several time points during the study. Additionally, we would like to interview a small group of caregivers to find out more about their views and experiences. We are interested in looking at the impact on caregivers with hospital drains compared with use of home drains

3. Do I have to take part?

No, you do not have to take part. Your participation is completely voluntary. If you decide to take part, you are free to withdraw from the study at any time and

without giving a reason. This will not affect the medical care the person you are caring for will receive.

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

Once you have had enough time to read this leaflet you will have the opportunity to ask questions and decide if you would like to take part. If you do, we will ask you to sign a consent form.

At a date and time that is convenient for you, the research nurse or doctor will ask you to complete a questionnaire. As far as possible, this will be done at the same time as the research nurse or doctor does the assessment for the person you are caring for. The questionnaires will be completed online on smart phones. However, if you prefer they can also be completed over the telephone.

The questionnaire asks about the impacts to you of caring for someone with cirrhosis and ascites. You can take your time to answer the questions and it usually takes about 10 mins to complete. The questionnaire will need to be completed at the baseline visit and then every four weeks for a maximum of 12 weeks (four times in total or about 40 minutes of your time).

There will also be an opportunity to take part in an optional interview. We would like to ask you questions about your experiences of caregiving, and your experience about hospital drainage compared to drainage via the home drain (LTAD). If you are willing, we will ask your permission to pass on your contact details to the interview researchers. The interview researchers will contact you via phone once you have had enough time to read this leaflet and consider this research. If you wish to participate the interview researcher will answer any questions or concerns you may have. Verbal consent for the interview will be taken over the phone. We hope 20 caregivers will take part in the interviews.

The interview will last between 15-45 minutes. The interview will be audio recorded. Your interview will be written down anonymously (i.e. without your name or identifying details) and the audio recording will be destroyed.

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

Since participating in this study requires you to complete questionnaires and taking part in an interview no major risks are anticipated. However, it is possible that answering some of the questions may cause distress. Should this happen, please contact the study team.

6. What are the possible benefits of taking part?

You are unlikely to benefit directly from taking part in this research study. However, your views and experiences may help determine if home drains (LTADs) are an option for people with cirrhosis

7. What happens when the research study stops?

At the end of the study you will continue to care for your family member or friend as before.

8. What about my data and confidentiality?

The University of Sussex is sponsoring this study and will act as data controller; we will be responsible for maintaining and safeguarding your information. We will only use information that we need to carry out this research. All information collected about you will be kept strictly confidential to ensure compliance with data protection legislation that researchers follow.

How will we use information about you?

We will need to use your information for this research project. This will be collected from from you and include information about you and your caregiving role. 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 you safe and secure. 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. The anonymised research data will be stored electronically, for analysis, publication, and audit and retained in line with University of Sussex records retention policy, which can be accessed here: http://www.sussex.ac.uk/ogs/policies/information/recordsmanagementguidance

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 specific ways 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/
The university's privacy notice can also be found here: https://www.sussex.ac.uk/about/website/privacy-and-cookies/privacy
All personal and research data will be stored and processed according to the UK Data Protection Act (2018).

9. 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.

10. What if relevant new information becomes available?

Sometimes during the course of a research project, new information becomes available about the intervention being studied. This is unlikely to affect the questionnaire or the interview other than the possibility of additional questions to explore your experience in relation to the new information.

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 it impacting the care your family member/friend receives.

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.

13. What will happen to the results of the research study?

The results of the research study will be written up and published in scientific journals and presented at medical conferences. A lay summary of the results will be available for participants. Your personal information will not be identifiable in any way. If you would like to be sent or emailed a copy, please give us your contact details.

14. Who is organising the research?

The University of Sussex are overseeing the conduct of the study, alongside the Chief Investigator and the Brighton and Sussex Clinical Trials Unit (BSCTU). The universities of Brighton and Sussex have insurance for any liabilities arising from this research.
The questionnaire and interview component of the study is being led by researchers from the Sussex Health Outcomes Research and Education in Cancer (SHORE-C) at the University of Sussex. The study is funded by a grant from the Department of Health (National Institute for Health Research). Your doctor or the researchers will not receive any personal financial payment if you take part.

Your doctor or the researchers will not receive any personal financial payment if you take part in this study.

15. 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 Oxford REC Committee (REC reference number 22/SC/0164).

16. Contact for further information

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

Dr Yazan Haddadin, Clinical Research Fellow
Tel: 07881 326775

Please insert local site details here:

For further information about the interviews you can contact SHORE-C REDUCe 2 Team at Brighton and Sussex Medical School
University of Sussex
Science Park Road, Falmer, Brighton, BN1 9RX
Phone: 01273 873019
Email: shorec-reduce2@sussex.ac.uk

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