Brighton and Sussex Clinical Trials Unit

REDUCe 2

**NEWSLETTER ISSUE #4 – March 2023**

# REDUCe2

Palliative Long-term Abdominal Drains Versus Repeated Drainage in Untreatable Ascites Due to Advanced Cirrhosis: A Randomised Controlled Trial

## RECRUITMENT UPDATE (as of 31st March 2023)

A total of **15** participants have now been randomised. Congratulations to Bolton and Brighton who have both randomised patients in March.

The top recruiting site is UHSussex – Brighton with 8 patients

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## SITE NEWS THIS MONTH

### New sites opened:

- St George's University Hospitals NHS Foundation Trust - St George's Hospital
- University Hospitals Plymouth NHS Trust – Derriford Hospital
- NHS Grampian – Aberdeen Royal Infirmary
- Northumbria Healthcare NHS Foundation Trust – North Tyneside General Hospital

### SIVs have taken place at:

- Cambridge University Hospitals NHS Foundation Trust – Addenbrooke's Hospital

### SIVs are planned at:

- Cwm Taf Morgannwg University Health Board - Royal Glamorgan Hospital

Don't forget to follow us on **TWITTER** using **@REDUCe2Study** for the latest study news!

## CONTACT DETAILS

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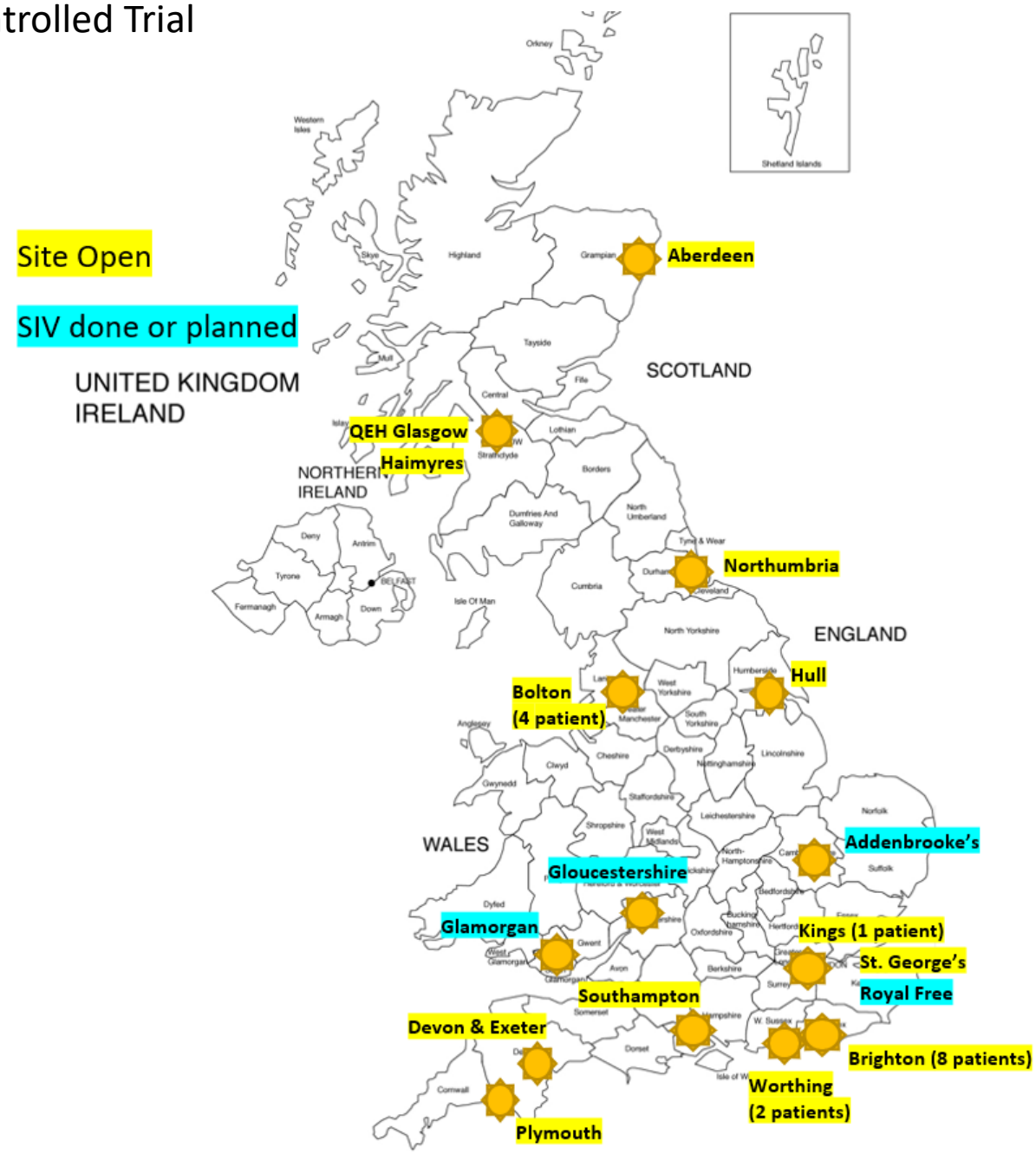
## Palliative Long-term Abdominal Drains Versus Repeated Drainage in Untreatable Ascites Due to Advanced Cirrhosis: A Randomised Controlled Trial



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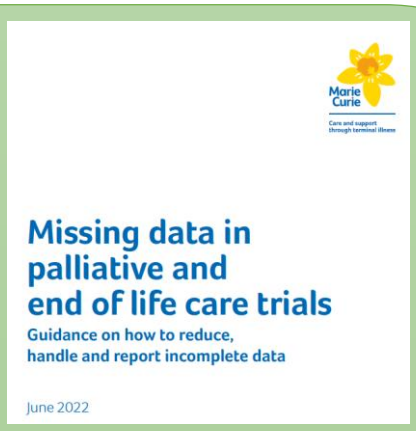
## Palliative Long-term Abdominal Drains Versus Repeated Drainage in Untreatable Ascites Due to Advanced Cirrhosis: A Randomised Controlled Trial

New guidance has been published by **Marie Curie** about palliative care trials:

There are 3 main sections:

1) How to **reduce** missing data in palliative and end of life care trials
2) How to **handle** missing data in palliative and end of life care trials
3) How to **report** missing data in palliative care trials




https://www.mariecurie.org.uk/missing-data

The guidance is intended to provide PPI research partners, researchers, data collectors & statisticians with a framework for how missing data should be addressed throughout the trial.

Guidance on how to reduce missing data includes:

- Adequately training sites to understand the risks posed by missing data and how to minimise this
- Discussing the value of complete data & how to reduce missing data with participants before they consent
- Distinguishing participants who want to withdraw from providing any further data from participants who wish to withdraw from part of the trial but consent to ongoing data collection
- Monitoring and addressing missing data during the trial

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## MEET THE TEAM

**Joan Bedlington, MBE – PPIE representative for LIVErNORTH**
Joan was recently awarded an MBE for 'Services to Liver Patients'

**PPIE - Being involved -is it important?**

The simple answer is yes, however, it might not appear that simple to everyone.

Patient and Public Involvement and Engagement (PPIE) gives you an opportunity to consider research proposals, give your opinion on the relevance of a proposal and to be involved in the design and methodology of research projects. Patients and members of the public are able to share their views, ideas and experiences; in doing so they are able to contribute to ongoing and future research in partnership with medical and research teams.

It is important to stress that involvement is not exclusive. Depending upon your personal experience, circumstances and preferences, anyone can contribute through raising new research questions, assisting in the development of patient information documentation and publicising study findings.

*Continued overleaf.*

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Key to the success of any collaboration is the need for mutual respect and the acceptance of differing opinions. I have been involved with the REDUCe2 study since being approached by Professor Verma who was looking for lay people interested in being part of the research team. From the outset it has been a positive experience. Everyone has been welcoming, the research proposals and design have been discussed with the researchers and fellow team members, all of whom have openly expressed their views with no apparent hesitation. It is clear to me that opinions have been listened to and that the contributions from everyone are seen as a valuable resource to the REDUCe2 study.

One positive outcome of the pandemic has been the opportunity for people to meet virtually. It is not always convenient or possible for people to travel around the country, however, through Zoom meetings the opportunity to connect with others has been broadened.

Never underestimate the value of your opinion: my experience with the REDUCe2 Study has been positive throughout, I have learned so much from the researchers, academics, nurse specialists, consultants and it is my hope that they have also found it beneficial to have input from a lay person.

**So, is being involved important? Simple answer: Yes**

Joan Bedlington, MBE

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### MEET THE TEAM

**Dr Helena Harder, Senior Research Fellow**
**&**
**Rachel Starkings, Research Fellow – SHORE-C, University of Sussex**

We are undertaking a series of semi-structured interviews with patients, informal caregivers and healthcare professionals (HCPs). The conversations with patients and informal caregivers will add further detail about the lived experience of the disease, including impact on QoL, and of taking part in REDUCe2.

Our discussions with HCPs will tell us about what it's like to work with this patient cohort and recruit to this study. We aim to complete 30 interviews with patients, 20 with caregivers and 20 with HCPs, from different sites and spaced throughout the course of the study. The interviews will be used to help interpret study results along with informing communication training workshops offered to sites as part of this study.

If a patient or caregiver is interested in having an interview, please complete the EOI form and email to reduce2@bsms.ac.uk

If you are a healthcare professional interested in having an interview, please contact the SHORE-C team directly via shorec-reduce2@sussex.ac.uk

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### HOUSEKEEPING

### SAEs / SARs

- Please remember that **only potential SARs** need to be reported via email immediately when sites become aware of the event, and at least within 24 hours to: BSCTUsafety@bsms.ac.uk
- AEs / SAEs, ARs / SARs should all be documented in the eCRF
- An **SAR** is an adverse event that is both serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to one of the study interventions, based on the information provided.
- If a patient gets randomised and dies prior to receiving the intervention this should be documented as an SAE.

### Visit schedules

If there are any problems with the LTAD and it needs to be reinstated, the 'visit schedule' clock starts when the first drain is inserted. All future visits should be calculated from that date.

### Study Supply Re-ordering

| Item | Initial Supplies | Re-ordering |
|---|---|---|
| LTAD kits (Rocket Medical) | 2 drainage kits | Sites should email CustomerServices@rocketmedical.com once an LTAD has been used. Sites to put 'REDUCe2' in the email header |
| Blood kits for optional sample | 2 kits | Sites should email dominika.wlazly@nhs.net |
| LTAD Drainage Diaries | 20 | Sites should email reduce2@bsms.ac.uk |