



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 July 2023)

A total of **29** participants have now been randomised.

Congratulations to Queen Elizabeth Hospital Glasgow, Royal Devon & Exeter, Plymouth, Aberdeen, St George's & Southampton who have all recruited their first patients!

Site	Number of patients
BRIGHTON - RSC01	10
SOUTHAMPTON - UHS02	1
NHS GRAMPIAN (ABERDEEN) - ARI05	2
QUEEN ELIZABETH GLASGOW - QEG07	1
LANARKSHIRE - HAI08	1
ROYAL DEVON & EXETER - ROY13	1
ST GEORGE'S -STG17	1
KINGS - KCH18	2
WORTHING - WOR19	4
BOLTON - BOL21	5
PLYMOUTH - PLY28	1

Go to Page 5 to read some inspirational quotes from REDUCe2 study participants.



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SITE NEWS May, June & July

New Sites Open:

- Cambridge University Hospitals NHS Foundation Trust – Addenbrookes Hospital
- Guy's & St. Thomas' NHS Foundation Trust – St. Thomas' Hospital and Guy's Hospital
- Gloucestershire Hospitals NHS Trust - Gloucestershire Royal Hospital
- Cwm Taf Morgannwg University Health Board - Royal Glamorgan Hospital

SIVs have taken place at:

- Nottingham University Hospitals NHS Foundation Trust - Queens Medical Centre
- The Newcastle Upon Tyne Hospitals NHS Foundation Trust – Freeman Hospital
- Liverpool University Hospitals NHS Foundation Trust - Royal Liverpool University Hospital

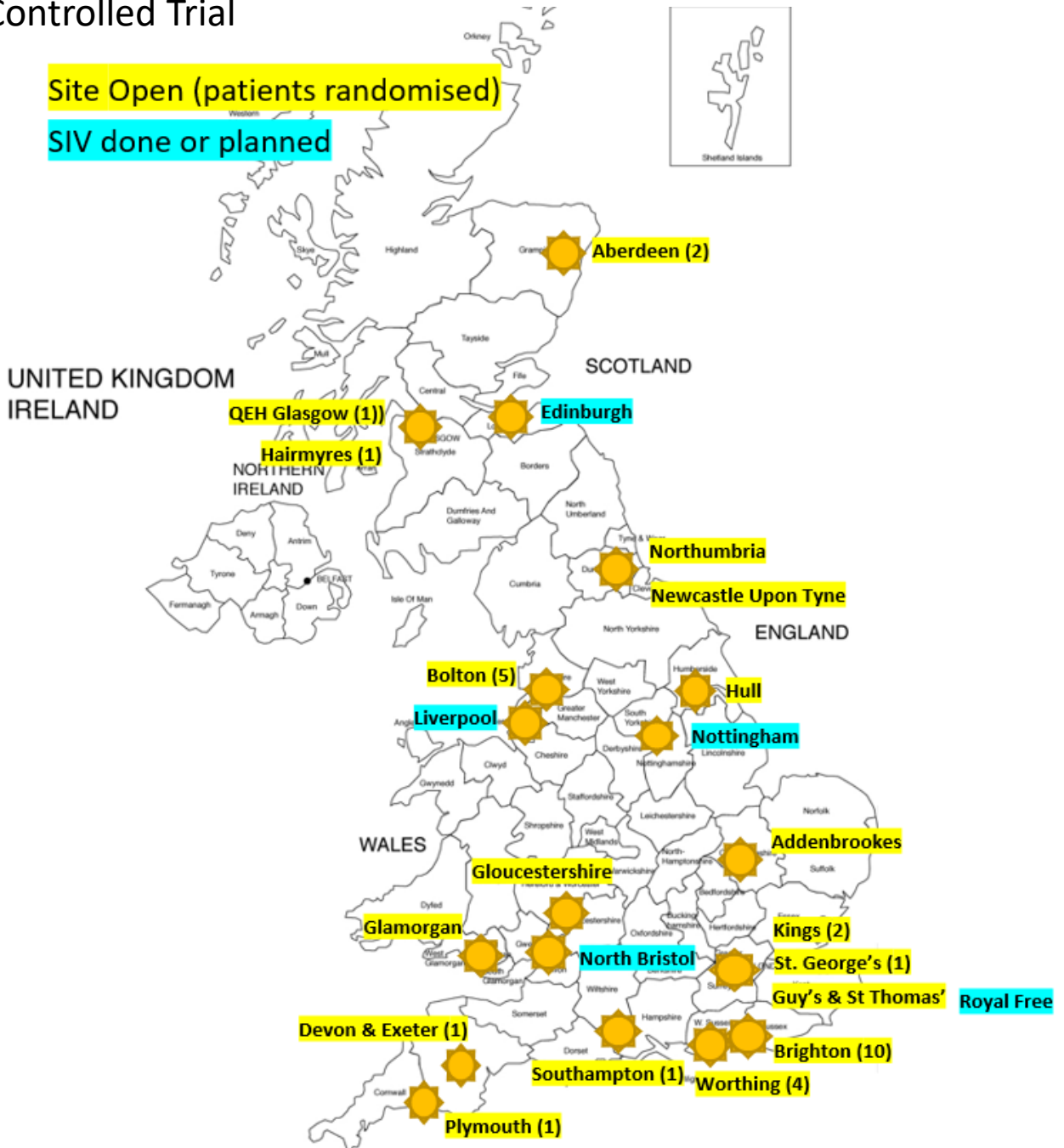
SIVs are planned at:

- NHS Lothian – Royal Infirmary of Edinburgh



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Meet the Team: Bolton NHS Foundation Trust – Bolton Royal Infirmary



From left to right – Heather Riley, Dr Mahesh Bhalme, Sam Osbourne, Emma McKenna, Dr Kirsty Nixon

The Bolton Reduce 2 team is made up of two Consultants Dr Mahesh Bhalme (PI) and Dr Kirsty Nixon (Co-Inv), 1 amazing Liver Specialist Nurse/ Alcohol Team Lead Sam Osbourne, 1 senior clinical research Practitioner Emma McKenna and 2 research Nurses Heather Riley and Julie Chadwick and Rebecca Flanagan who started on the trial as a CTA and is now a research Practitioner.

We have also had the support of the District Nursing teams, the hospice at home team and the palliative care team whom we would struggle to do the study without their support.

I hadn't worked in this area of research before and so it did seem quite a daunting prospect, but my fears were unfounded the entire Reduce 2 study center have been amazing offering us support with all our many questions and queries.

The patients have all had an overwhelmingly good experience of the trial and the opportunity it has given them to get some sense of normality back in their lives.

It's been such a rewarding trial to be involved in because of the experience the patients have had and seeing the patients regularly has allowed us to build up a true picture of how the trial is making a difference to even the small things in their lives allowing them to be able to cook and clean for themselves and relieving some of the stresses they felt they had trying to get into hospital to be drained.

We have only had patients in the LTAD arm so far and none in the LVP arm but for us as a site this has been a positive because all the patients have benefitted.

Emma McKenna, Senior Clinical Research Practitioner



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Positive Feedback from Participants

One of the 1st participants in the study from Bolton was happy share her thoughts about the impact of the study on her life:

“Since joining the trial I have become much more mobile. I’ve been planning trips, going to concerts and recently spent a day in London enjoying an afternoon tea. It’s the small things too though as I can now move independently around my home.

The whole trial has been a positive experience from start to finish. The extra support provided by the research team has made a massive difference to my life, and my family’s, and having people on hand for any questions I had was invaluable.

Taking part in research has given back some control in both of our lives, and we hope it will help others struggling with the same condition in the future.”

Her husband added:

“It’s great to see how the trial has transformed my wife’s life, but it’s had a positive impact on mine too. My mental health has improved as we’re spending less time in hospital and spending more time managing the condition at home.”

A second participant at Bolton said:

“Being part of this study and being randomised to LTAD treatment has completely changed my life for the better, it’s given me a better quality of life and shown me a semblance of normality”

Thanks to the patients and relatives from Bolton for allowing us to share these comments with everyone.



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Filming for Communication Skills Workshops



Filming for the planned Communication Skills Training days took place on Friday 28th July at SHORE-C, University of Sussex.

Professional actors were used alongside two Gastroenterology Consultants – Dr Khaleel Jamil and Dr Ziva Mrevlje from University Hospitals Sussex NHS Foundation Trust.

Two realistic patient consultation scenarios were filmed for group discussions and practice at the workshops.

More details about the days will be announced soon. We hope that you will find them useful.





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Housekeeping

Long Term Abdominal Drains:

Rocket Medical

The full IPC insertion kits are now available from Rocket Medical.

LTAD drainage kits and additional drainage bags can be ordered directly from RM. Please email - customerservices@rocketmedical.com (remember to put REDUCe2 in the email header)

BD PeritX™ Peritoneal Catheter System

The company has now confirmed that these will be supplied for the study for those sites wishing to use them. We are hoping to supply these shortly.

SAEs / SARs:

Remember that only potential **SARs** need to be reported via email to us – bsctusafety@bsms.ac.uk

SAEs should be documented in the eCRF as normal, An updated SAR reporting guidance form (V3.0 3.4.2023) and SAR form (V3.0 3.4.2023) have been sent to all sites. The eCRF has been updated and an alert has been added to remind sites to report an SAR to BSCTU.



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Recent Protocol Amendments **Amendment 06 – Non-Substantial**

Approval of updates to Patient PIS (V4.0 04.04.2023), Patient consent form (V3.0 03.03.2023) and Modified AHCR Questionnaire (V2.0 12.0.42023). Plus, translation of some documents into Welsh and Urdu.



Please make sure you are using the correct versions



Documents to Email after Consent

Please remember to email the following documents to reduce2@bsms.ac.uk within one week of randomisation:

- Patient consent form
- Eligibility checklist – signed by PI / Co-PI
- Caregiver consent form (if applicable)
- Expression of Interest forms for Patient and / or Caregiver (if applicable)



Please make sure they are emailed securely



LTAD Ascites drainage Diaries

A new version of the LTAD diary has been printed (V2.0 31.05.2023). Copies have been sent to all sites for immediate use.



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Study Website – coming soon.....

We are in the process of setting up a website for the study. This will be accessible by sites and patients. Sites will be able to access site resources and there will be a comprehensive FAQ section.



Follow us on **TWITTER** using [@REDUCe2Study](https://twitter.com/REDUCe2Study) for the latest study news!

Next Newsletter will be October

CONTACT DETAILS

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