

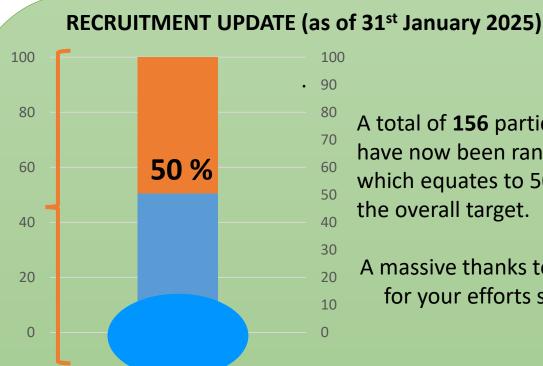


NEWSLETTER ISSUE #12 - January 2025



REDUCe2

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



A total of **156** participants have now been randomised, which equates to 50% of the overall target.

A massive thanks to all sites for your efforts so far!!

However, there's still a long way to go we still need 8 -11 randomisations per month!! We can do it!

Congratulations to the Study Team at Sheffield who won the draw for sites recruiting patients 150 to 155. Enjoy your prize!





SITE NEWS November, December & January







Study Team news

Protocol paper

The protocol manuscript has been submitted to Trials for publication. Not sure what they are about? Find out more here:

Home page | Trials

Plymouth press release

The Study Team at Plymouth wrote an article about REDUCe2 which was published on the University Hospitals Plymouth NHS Trust website in December. You can read it here:

<u>UHP recruits 100th patient to study aiming to improve quality of life for advanced liver disease patients | Latest News | University Hospitals Plymouth NHS Trust</u>

Assisted Dying Bill

The Assisted Dying Bill was presented to the House of Commons in November, and it has brought the issue around Palliative Care and End of Life care to the forefront. There is an Independent Commission on Palliative and End of Life Care currently ongoing, in which there will be a session on research, chaired by Prof Sir Mike Richards. There is currently a call for written evidence (deadline is 28th March 2025).

More information about submitting evidence and the evidence schedule can be found at: https://palliativecarecommission.uk/

An oral evidence session on Research and Innovation is being held on Zoom on 27th February 2025.







The RAMONA Study

Dr Ben To – Academic Clinical Fellow at UHSussex NHS FT will be doing a national audit of patients with refractory ascites as a follow-on from REDUCe2.

Want to get involved in a gastroenterology national audit?



REFRACTORY ASCITES:
MANAGEMENT AND
OUTCOMES – A NATIONAL
AUDIT (RAMONA)







Site registration period: 20th January 2025 – 30th June 2025 Data submission deadline: 30th November 2025

Please contact Ben To (b.to@nhs.net) for further information on how you can get involved!

The audit will be looking at outcomes and treatments of patients with refractory ascites – patient demographics, UKELD, MELD & Child Pugh scores, LTADs and LVPs, TIPS and liver transplants. Patients need to have had at least 3 LVPs during 2018 and data on treatments received during 2019 will be collected. Data will be collected on REDCap.

Sites have until 30/06/2025 to register. Please contact Ben To for more information – b.to@nhs.net







SHORE-C News REDUCe2 Communication Workshops

The next two facilitator-led 1-day communication courses with interactive, didactic presentations, group exercises & discussions are fast approaching.

Edinburgh Only a few places left

The George InterContinental Hotel - Monday 3rd March 2025





Birmingham (currently full)

Hyatt Regency Hotel on Tuesday 4th March 2025

Workshops are suitable for any REDUCe2 core multidisciplinary team member and attract CPD points. Attendance is **FREE** with refreshments and lunch provided.

Sites can claim back up to £100 travel expenses for 2 participants.

Qualitative Interviews

We are still looking for Healthcare Professionals to take part in the interviews with SHORE-C. We can be flexible on times.

If you're interested, please email Rachel or Helena at shorec-reduce2@sussex.ac.uk





Top Tips & FAQs

Reporting of SAEs / SARs

Only Serious Adverse Reactions (serious events 'possibly, probably or definitely' related to the intervention) need to be reported using the forms. Serious Adverse Events should be documented in the eCRF.

Current version is REDUCe2 Non-CTIMP SAR Form v4-15Aug2023

Please remember that the Causality Assessment section needs to be completed by a PI or Co-PI who is on the Study Delegation Log for that role.

Participant Withdrawals and Deaths

Please remember to inform the study team immediately of any participant withdrawals and deaths. This ensures SHORE-C are aware and don't contact them or their Caregivers for the Qualitative Interviews.

AEs / ARs / SAEs / SARs post 12 Weeks

There have been instances of patients having clinical events after the 12-week study period which is not unexpected in such a cohort. For purposes of the current study, we are only recording events (AE/AR, SAE/SAR) occurring up to 12 weeks. However, we do aim to collect long-term outcome data as a separate post hoc analysis so events occurring after 12 weeks will eventually be captured.

Brighton and Sussex Clinical Trials Unit Strighton and sussex medical school





Top Tips & FAQs

Calculating HAS for MACRO

1 unit = 100ml solution containing 20g Albumin. The units in MACRO are in grams, therefore 500ml HAS given should be reported as 100g.

Modified AHCR Questionnaires

Should be completed every **2 weeks** from **Baseline** even if there is no caregiver.

Where there is **no caregiver** patient to complete:

Section 1: Health and Social Care Visits / Appointments Inside the Home

Section 2: Healthcare Visits / Appointments / Stays Outside the Home

Section 3: New Supplies and Equipment (Weeks 2 onwards only)

Section 5: Participant Symptom / Functional Assessment (caregiver or

participant)

Section 7: Out-of-pocket Expenditures

Caregiver only to complete:

Section 4: Caregiving

Section 6: Caregiver's Burden Scale In End-of-life Care

Section 8: Caregiver Views about Healthcare and Social Services Received

Short-Form Liver Disease Quality of Life Questionnaires

This is our Primary Outcome measure so please double check that **all questions** have been answered in each section before you leave the patient.

Please use the **Headed** version of the questionnaire.





KEY CONTACTS

General study queries & Sealed Envelope password resets:

Alison Porges (Trial Manager) reduce2@bsms.ac.uk

Tel: 07721 860469

Dr Yaz Haddadin (Clinical Research Fellow): yazan.haddadin@nhs.net

Tel: 07881 326775

eCRF queries or password resets:

Gina Richards (Data Manager): <u>G.Richards@bsms.ac.uk</u>

or Debbie Lambert (Database Manager): D.Lambert@bsms.ac.uk

Database for SFLDQoL & CRRS Questionnaires & Interviews:

SHORE-C Team: shorec-reduce2@sussex.ac.uk

Tel: 01273 873019

Additional blood kits:

Dominika Wlazly: dominika.wlazly@nhs.net or uhsussex.crf.lab@nhs.net

Additional Rocket Medical LTAD Insertion Kits & Drainage Bags / Bottles:

Customer Services: customerservices@RcoketMedical.com

Additional BD (PeritX) LTAD Insertion Kits & Drainage Bottles:

Contact your local BD rep



Follow us on X (TWITTER) - @REDUCe2Study Website - https://www.reduce2.co.uk

Next Newsletter will be May 2025