Brighton and Sussex Clinical Trials Unit
brighton and sussex medical school

REDUCe 2

NEWSLETTER ISSUE #9 – April 2024

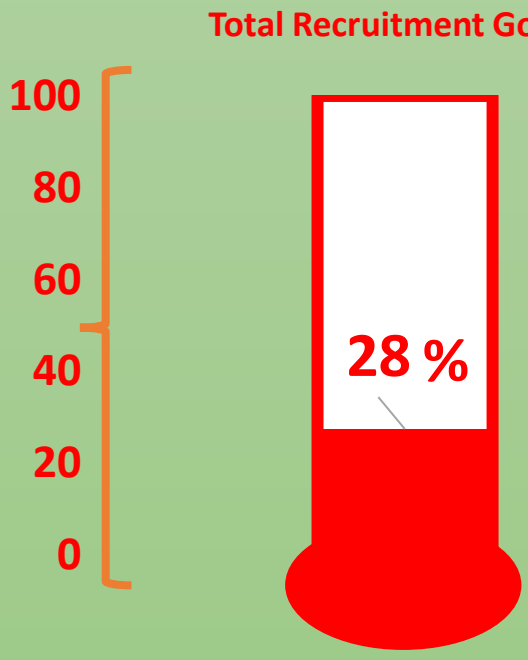
REDUCe2

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

An immense thank you to Brighton research team, BSCTU and all our sites for the successful completion of the 12-month pilot. Onwards and upwards,
Prof Sumita Verma

RECRUITMENT UPDATE (as of 30th April 2024)

A total of **87** participants have now been randomised.



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SITE NEWS February, March & April

SITES OPENED

- **Barts Health NHS Trust** – Royal London Hospital
- **Sheffield Teaching Hospitals NHS Foundation Trust** – Northern General Hospital
- **South Tees Hospitals NHS Foundation Trust -** James Cook University Hospital

SIVs DONE

- **Royal Surrey NHS Foundation Trust** – Royal Surrey County Hospital
- **Royal Cornwall Hospitals NHS Trust -** Royal Cornwall Hospital

Communication Workshop

The first workshop took place on Tuesday 23rd April in London and was fully booked. A big thank you to all delegates for their participation, making this a successful event.

We had fantastic feedback and 100% of participants would recommend the workshop to other REDUCe2 teams. Pre and post assessments showed attendance improved the self-confidence of participants when discussing trials in general and REDUCe2 with this patient population.

Some feedback from the day:

Networking and discussing with other practitioners was really helpful

Ensuring how to recruit to the trial. Recognising challenges of others who have recruited more patients and the challenges that have arose and how to deal with them.

Raised awareness of how much of our language is not understood by the patient

There are still places available for the workshop in Bristol on Thursday 9th May.

Please contact us via shorec-reduce2@sussex.ac.uk to register your interest.

Dates and locations for the autumn workshops will be released soon!

Meet the Team …….

University Hospitals Birmingham NHS Foundation Trust - Queen Elizabeth Hospital

Dr Neil Rajoriya, Consultant & Principal Investigator, Emma Burke Senior Research Nurse, Sara Bardell CNS Hepatology, Joanne McDonagh CNS Hepatology, Isobel Hayes CNS Hepatology

We as a team at Birmingham Queen Elizabeth Hospital were excited to be recruiting to REDUCe 2 – getting the site up and running was a long time coming! Having had clinical experience (along with published datasets) with long term ascitic drains and contributing to the national consensus development we felt driven to be involved.

We believe being part of this trial will provide us with the much-needed evidence to enable us to offer the safest treatment options to our patients. Ascites causes such significant burden to patients and their caregivers.

Left to right: Jo, Neil, Emma and Sara

The REDUCe 2 trial has been successful so far as the Research team have been working with the Hepatology Clinical Nurse Specialists who work so closely with this group of patients in delivering the best care possible through the clinical trial.

Sara, Izzy and Jo manage the nurse led paracentesis service so screening eligible patients has been easy to do. Because we know the patients so well, we know where they are in future management options and most often, we have titrated diuretics in clinic, so we know we have explored all ascites management options. Any potential recruits are discussed at our weekly pan-Birmingham cirrhosis MDT we convene. This ensure all criteria are met, and trial processes duly followed. Using this pathway, we managed to recruit 3 patients in 3 days at one stage.
Our team has been involved in research in the past to varying levels so completing good clinical practice was a good learning experience. Dr Rajoriya, Emma, and the research team have supported us to be involved in consent and data collection.

By far the best part of this study for us has been the home visits. It has been a privilege to be welcomed into our patient's home and seeing them in their own environment. Sometimes difficult to leave when offered tea, biscuits, and a good catch up.

Our first patient in the LTAD group has felt that the LTAD has been life changing. He can do more and feels less of a burden to his wider family with less hospital visits.

The reduce team Alison, Professor Verma, Yaz and team have been helpful, the study is well -led and we can ask questions at any time with a speedy response.

Joanne McDonagh

Data Entry Top Tips!

Unused ‘study subjects’ on eCRF

Try not to add unnecessary study subjects prior to randomisation. Any unused subjects should be used first for new participants.

Study	Site	Subject ID	Subject Label
All Studies			
REDUCE2		1	
REDUCE2		2	
REDUCE2		3	R 001
REDUCE2		4	R 002
REDUCE2		5	
REDUCE2		6	
REDUCE2		7	
REDUCE2		8	

Adverse Events

Please don’t use ‘Hospitalisation’ or ‘Death’ as the Event Description. Please refer to the CTCAE v4.03 for the correct terminology.

Common terminology criteria for adverse events (CTCAE, version 4.03) will be used for assessing AE/SAE/AR/SARs

Event Description

If an event is ‘intermittent’, e.g. intermittent leakage, the stop date can be left open, rather than record as separate events. Examples - leakage or encephalopathy.

Death due to End Stage Liver Disease doesn’t need to be added as a Serious Adverse Event on the Adverse Event page. However, the Withdrawal page and End of Study pages should be completed.

Please make sure the Randomisation page at the Baseline visit is completed in a timely manner. This helps reduce missing data when assessing adverse reactions.

Documents to be sent after randomisation

Please send the following documents to reduce2@bsms.ac.uk via **Secure** email:
- Patient consent form
- Eligibility Checklist – signed by PI / Co-PI to confirm eligibility
- Caregiver consent form (if applicable)
- Expression of Interest forms for the Qualitative Interview for the patient and / or caregiver, if applicable. These will then be forwarded to SHORE-C.

These should be sent within 1 week of randomisation.

Next Newsletter will be July 2024

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

WHO TO CONTACT

General study queries:

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Dr Yaz Haddadin (Clinical Research Fellow): yazan.haddadin@nhs.net
Tel: 07881 326775

eCRF queries or password resets:

Debbie Lambert (Database Manager): D.Lambert@bsms.ac.uk
Tel: 01273 641675

Database for SFLDQoL + CRRS Questionnaires and 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