Welcome to…

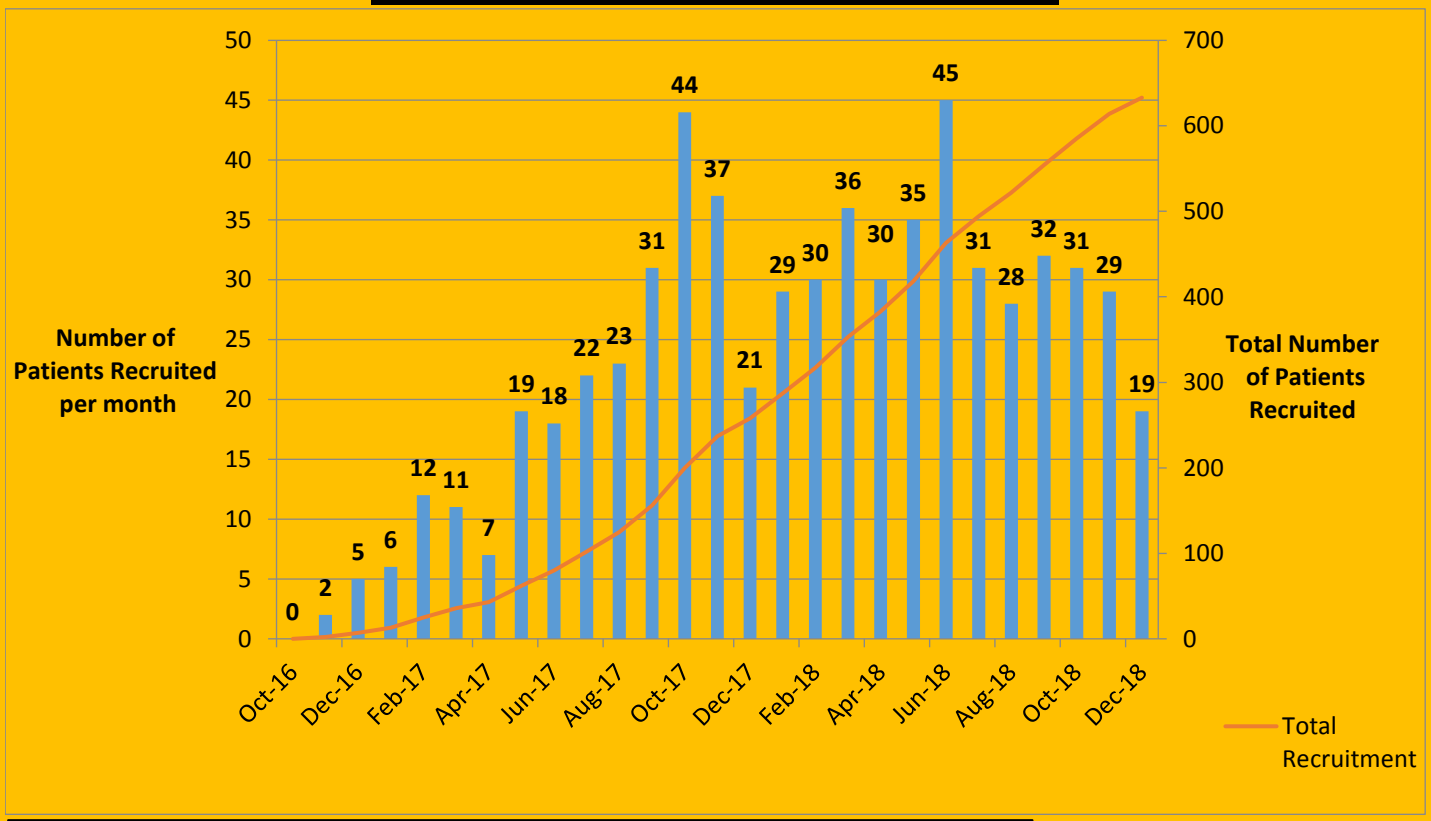
The BHF SENIOR-RITA Trial Newsletter

Issue 11: December 2018

TOTAL RECRUITMENT: 633 PARTICIPANTS

- Thank you to everyone for your commitment and dedication to SENIOR-RITA
- We have recently passed the 600th participant milestone however we are still a long way from reaching our target which is 2300 participants
- Our weekly target is **16-20 patients** and with 40 sites recruiting this is achievable with all your ongoing enthusiasm and support!

UK wide BHF SENIOR-RITA recruitment



- ***We ask that you continue to keep up the enthusiasm and continue with the recruitment- EVERY PATIENT COUNTS!***

BEST PRACTICE IN RECRUITMENT

- Let your entire team (Junior doctors, MAU, Wards, CCU, COE team) know about SENIOR-RITA
- Use the posters and stickers to publicise the study at your site
- Use the recruitment video and share with your patients and colleagues
- Make contact with patients early before a decision is made
- Regular reminders, education sessions, prominent presence of SENIOR-RITA research staff on the wards

We would like to thank each and every one of you for all your great work this year in SENIOR-RITA.

We still have a long way to go, therefore keep up the enthusiasm and continue recruiting!

From all of us here in the SENIOR-RITA office, we wish everyone a peaceful Christmas and very best wishes for the New Year

Unique features of SENIOR-RITA

- With 633 patients recruited so far, already making SENIOR-RITA the *world's largest trial!*
- However, we really need to analyse a lot of prespecified subgroup analysis including frailty, co-morbidity, cognition etc. Therefore it is vital that we keep going and offer all eligible patients the opportunity to take part in SENIOR-RITA
- Thus far we have recruited exactly the sort of patients we need for this trial!
- We provide below some of the baseline data of 508 patients recruited so far to SENIOR-RITA
- We thank you for your hard work, but we ask that you continue your fantastic efforts so we can reach our overall sample size as close as possible.
- The data is closely reviewed by the Data Monitoring Committee and they have advised the trial should continue as planned with no concerns in both treatment strategies so far!

SENIOR-RITA

Variables	Total sample size n=508	Medical therapy	Total sample size n=508
Age Median	83 years (Oldest 102 years of age)	Aspirin	89%
80+	71%	P2Y12	90%
85+	36%	ACEI/ARB	67%
Female	49%	Beta blocker	78%
Frail (Fried)	35%	Anticoagulant	24%
MOCA (Median)	24		
Charlson Median	5 (Severe)		
Creatinine not in normal range	30.7%		

THE BHF SENIOR-RITA TRIAL SITE LEVEL RECRUITMENT UPDATE AS OF 20 DECEMBER 2018

Site	Opened to recruitment	Recruited to Date
Aberdeen	04-Dec-17	5
Ayrshire & Arran	22-Mar-17	28
Borders	02-Jun-17	1
Dundee	13-Nov-17	12
Edinburgh	01-Dec-16	15
Glasgow - Royal Alexandra	28-Feb-17	6
Lanarkshire - Hairmyres	30-Mar-17	2
Basildon	02-Dec-16	12
Blackpool	15-Nov-16	23
Bradford	19-Jun-18	8
Chesterfield	30-Nov-16	34
Co Durham & Darlington	23-Jun-17	37
Derby	22-Sep-17	16
East Sussex	21-Feb-17	6
Epsom & St Helier	04-Aug-17	6
Gateshead	09-Dec-16	7
Imperial	22-Aug-17	1
Lincoln	27-Jan-17	15
Mid-Essex	30-May-17	9
Newcastle	31-Oct-16	104
North Cumbria	31-Jul-17	8
North Tees	23-Feb-17	60
Northumbria Healthcare	27-Mar-17	46
Plymouth	15-May-17	14
Royal Berkshire	03-Jul-17	2
Royal Free	03-Jul-17	7
Royal Oldham	13-Mar-18	2
Sandwell & West Birmingham	09-Jul-18	2
Sheffield	25-Jan-17	24
South Manchester	15-Mar-17	23
South Tees	02-Dec-16	42
South Tyneside	16-Dec-16	6
Sunderland	15-Mar-18	3
Surrey & Sussex	02-Jun-17	9
Torbay & South Devon	12-Jun-17	17
West Middlesex	26-Apr-18	5
Wrightington Wigan & Leigh	21-May-18	5
York	31-Aug-17	11
	TOTAL	633

We are delighted to welcome Professor Colin Berry and Team from Queen Elizabeth Glasgow and Dr Veerasamy and Team (pictured below) from Leeds General Infirmary who will be joining our SENIOR-RITA team soon. We look forward to working with you!

Well done to Samantha and Dr Sultan from Wigan Royal Infirmary (pictured) for recruiting 5 patients in a short period!

Special thanks to SENIOR-RITA teams Arran and Ayrshire, Chesterfield, Durham and Darlington, South Tees, Northumbria, North Tees and Newcastle who have all recruited over 25 patients so far! Keep up the great work teams!!!

To assist newly opened sites and as a refresher to all other sites, please find below information to assist you in conducting this trial

SCREENING:

Each person eligible for SENIOR-RITA, whether or not recruited, must be recorded on the **MACRO Screening log: BHFSRita_Screen.** Screening numbers are manually allocated and consist of six numbers in the following format: the first two digits are your site number and the next four digits follow sequentially starting with 0001. We ask that the screening database be updated as soon as possible after each screening takes place.

RANDOMISATION DOCUMENTS:

Sites should send copies of the completed Consent form, Eligibility Criteria checklist and Participant Contact details form (plus Carer, if applicable) **within one week of randomisation** to the Newcastle Clinical Trials Unit (NCTU) using one of the following methods of transmission:

- via the following SOHO66 fax number - **0191 580 0987**

- Alternatively, you may transmit the information from an **nhs.net email** address to another **nhs.net email**. For SENIOR-RITA, the following **nhs.net email** account must be used – nctu.seniorrita.conf@nhs.net

- **Please do not send unsecured Personal Identifiable Data (PID) to Newcastle University email addresses**

- Where site staff do not have access to an ***nhs.net email*** address and the site does not have a ***fax*** facility for transmission of **PID**, you may transmit the information via a standard ***nhs.uk/ac.uk email*** address provided that the information is **encrypted and password controlled** prior to transmission and sent to seniorrita.support@newcastle.ac.uk Sites should contact their local IT department for advice on the encryption method to use.

Please note: PID should never be transmitted to NCTU when reporting SAEs. Please continue to report SAEs as previously via fax 0191 5800866 or email as a password encrypted file to soho66seniorrita@newcastle.ac.uk

ELIGIBILITY & CONSENT

The role of confirming the eligibility criteria for participants must only be assigned to the PI, a sub-investigator or another medically qualified person on the delegation log. The Eligibility Criteria Checklist must only be signed off by these delegated persons and not by the Research Nurses.

SENIOR-RITA allows non-medics to obtain consent. As instructed by Sponsor, it is a requirement for all non-medics who will consent patients to this trial to undertake nurse consent training. A Nurse Consent training record must be completed prior to non-medics consenting patients to the study and the delegation log must reflect this responsibility too – copies of both to NCTU please via seniorrita.support@newcastle.ac.uk

MACRO DATABASE AND DATA ENTRY

Please ensure all data is entered onto the SENIOR-RITA MACRO database in a timely manner.
We are currently reviewing all participants who have reached the one-year follow-up point. This is the primary outcome for the study and **it is vitally important that this data is input as a matter of priority.**

MACRO DATABASE AND DATA ENTRY (cont'd)

All missing data and responses to Data Clarification Requests (DCRs) **must** be completed within 1 month of DCR or request from NCTU.

- For any questions where the data is not available, right click the mouse and select 'change status' then 'not available'. This will prevent this question from being flagged as missing.
- In order to close a DCR after you have resolved the query simply right click on the DCR you have responded to and select 'respond to DCR' – you will then be able to place a comment on the DCR and clarify how the DCR has been addressed in the dialog box. Select OK and close the DCR browser before saving the subjects visit page. After the data has either been changed, verified or marked as 'not available' the red flag will change to blue. A member of the NCTU team will then be able to check all blue responded to DCRs and close them. Unless they are showing as blue flags, we will not know that you have responded.
- Death Form eCRF – please ensure the primary cause of death is provided and all subsequent data entered. The relevant Clinical Endpoint eCRF must also be completed to reflect the death.
- Study Withdrawal – please ensure the question asking 'has the patient withdrawn from follow-up' is completed and if yes, select the option to show what they have specifically withdrawn from.

We are planning to conduct a webinar about the SENIOR-RITA MACRO database in the new year. In this, we will be providing detailed instructions on completing the eCRF pages and providing useful hints and tips. Keep an eye out for the webinar invitation in our upcoming weekly recruitment emails.

SERIOUS ADVERSE EVENTS

Due to the nature of the study population (high-risk older patients with multiple co-morbidities) only serious adverse events which are causally related (i.e. possible, probable or definitely related) to the study intervention (coronary angiography and/or PCI) occurring within 7 days of the procedure will be reported in **patients randomised to the invasive arm only**.
Events occurring in participants randomised to the optimal medical therapy will not be reported as SAEs but will be recorded as an outcome measure in the eCRF.

Please mark your diaries for the upcoming SENIOR-RITA meeting:
Investigator meeting during BCIS ACI 2019 –
Hilton Meeting Room B, Second Floor, West Wing,
London Hilton Metropole
Thursday 17 January 2019 12.35-13.35

Please remember to keep checking The SENIOR-RITA website
https://research.ncl.ac.uk/seniorrita/
Also, don't forget to follow us on Twitter @SNR_RITA_Trial

Be sure to check our weekly updates on Monday mornings

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