

the POSNOC study

SITE NEWSLETTER - TWELVTH EDITION

DECEMBER 2020

POSitive Sentinel NOde: adjuvant therapy alone versus adjuvant therapy plus Clearance or axillary radiotherapy

"Total lockdown, compulsory face coverings, unthinkable hours Zooming and Teaming and now mass vaccinations. 2020 was both sobering and defining. The events brought new challenges for research that we were not prepared for. We were required to change the way we connect with each other and patients. Through it all, POSNOC continued to recruit with everyone's support, especially sites in Australia & New Zealand, and I am glad to say that we are due to complete recruitment on target in August 2021. In the coming years, we will need to focus on completeness of data and making sure all outcomes not just the first cancer event is recorded to enable the trial to provide a definitive result.



Amit Goyal, CI

Wish you a Merry Christmas and a VERY DIFFERENT NEW YEAR!!!"

1900
Goal

Current
recruitment
1768

2020 - WHAT a year!

The unpredictable year of 2020 is coming to an end and what a journey it has been!

Although 2020 has been full of inconsistent events, one CONSISTENT thing has happened - POSNOC is still hitting the target!

8 months left of the recruitment period, the finish line is in sight for the huge total target of 1900 participants! The

How POSNOC fits in with "the new normal"

- Remote consent can now be conducted remotely - a helpful step by step guide has been circulated with a cover letter you can use when posting out the ICF/PIS.
- ALL POSNOC follow up visits can be done over the telephone.
- Follow up clinic questionnaires can now be completed by post if unable to get hold of the participant on the telephone

Teleconferences in the new year

Keep an eye out for POSNOC teleconference invites that will be hosted in 2021.

These meetings will include ways to recruit, reminders about the pathways, any support we can give you as a CTU and give you a chat to ask any questions about the trial.



Christmas closures for NCTU

Nottingham Clinical Trials Unit (NCTU) is closed for the Christmas break from Monday 21 December 2020, returning to normal business on Monday 04 January 2021

SAES

Please continue to report SAEs in the usual manner by e-mail to nctu-sae@nottingham.ac.uk SAEs will continue to be monitored by the NCTU periodically during the Christmas break. You will receive confirmation of receipt within 1 working day; if you do not receive this confirmation please e-mail us again.

URGENT IT ISSUES

For any URGENT IT issues (e.g. unable to randomise a participant) during the Christmas break please e-mail ctu-it@nottingham.ac.uk This mailbox will be monitored by the NCTU during the Christmas break on the following dates: Monday 21 December to Thursday 24 December

RADIOTHERAPY REMINDER!

Radiotherapy CAN be given to the chest wall or breast using 26 Gy in 5 fractions

*****NB Treatment to the axilla and SCF are NOT permitted with 26 Gy in 5 fractions*****

Although there is some variability in opinion the majority view amongst UK clinical oncologists is that the 5 fraction FASTFORWARD radiotherapy schedule should not be recommended for routine use if any form of nodal irradiation, including to the axilla, is intended.

The FASTFORWARD nodal study is likely to be published in 2021 and this may influence this recommendation. For this reason, we do not recommend this dose/fractionation schedule in POSNOC if nodal irradiation is included, although it is permissible if radiotherapy is to be delivered to the breast or chest wall alone.



With quality of life being more important than ever, here is a message from SHORE-C...

We would like to thank everyone for their support during the past year. With your help, we have been able to continue sending SHORE-C questionnaires to POSNOC patients on schedule.

Do you have enough POSNOC patient information DVDs and baseline SHORE-C questionnaires?

Please contact Kathryn Monson: kmonson@sussex.ac.uk, to request further supplies.



Kathryn Monson, SHORE-C

Over the years - how POSNOC got here...

Opened in August 2014 you can see how over the years POSNOC recruitment has gone up and up and up and up etc etc

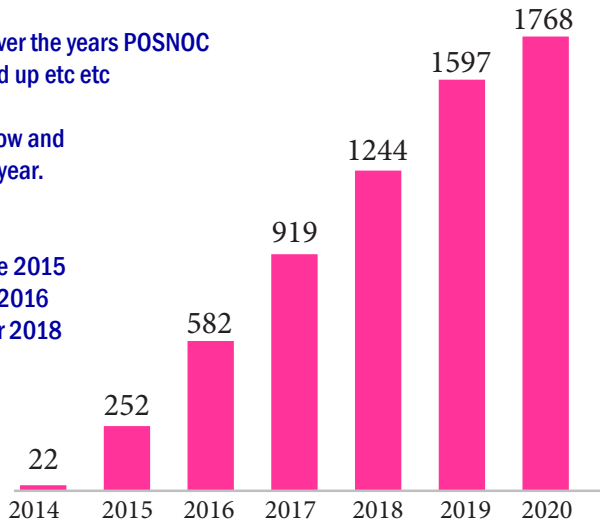
The big milestone dates have been put below and the graph shows recruit at the end of each year.

1st participant randomised 01-Aug-2020

- 100th participant randomised on June 2015
- 500th participant randomised in Oct 2016
- 1000th participant randomised in Apr 2018

Thank you to all 131 hospitals that have made this big achievement possible!

8 months left with less than a 150 to go!



National Institute for Health Research

