WELCOME TO THE FIRST EDITION OF THE ENDONET NEWSLETTER!

Welcome

Prof. Ramsey Cutress, Lead Investigator

Prof. Michael Douek, Chief Investigator

Welcome to the first e-newsletter of the EndoNET trial. The trial investigates whether neo-adjuvant endocrine treatment (NET) is effective in treating post-menopausal women with breast cancer.

The trial team, led by Prof. Ramsey Cutress and Prof. Michael Douek, would like to thank everyone for your continued support. If you have any questions, we would love to hear from you on: endonet@nds.ox.ac.uk.

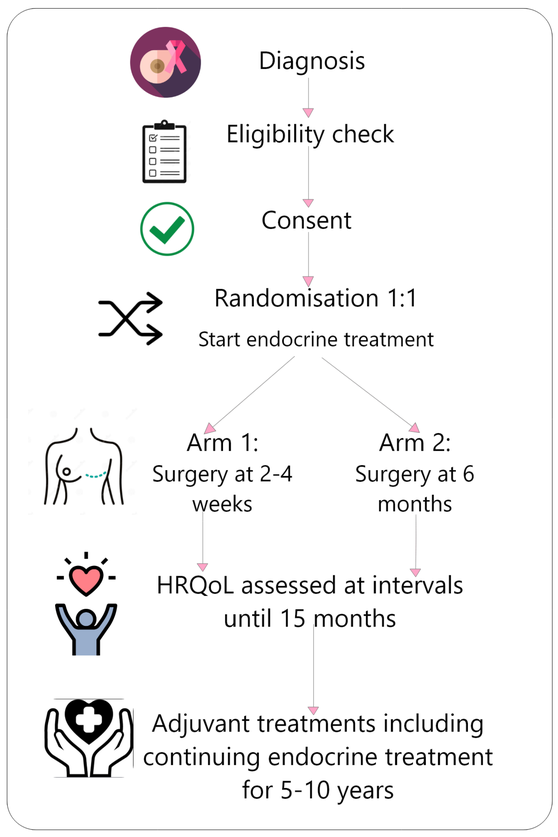
Trial Background

EndoNET is investigating whether endocrine treatment that prevents the production of oestrogens, when taken for 6 months prior to surgery, will shrink the tumour allowing for a reduction in the extent of surgery.

To be eligible, patients must be:

- Post-menopausal
- Strongly ER+
- HER2-
- Tumour ≥ 20 mm.

Participants are randomised to surgery at 2-4 weeks or 6 months and complete QoL questionnaires at intervals over 15 months and rates of breast conservation surgery will be documented.



Why does EndoNET matter?

- A potential **treatment option** for an under-represented part of the patient population
- First national RCT comparing the timing of surgery to see if **NET downstages the tumour** for those who are unlikely to require chemotherapy
- It aims to **reduce the number of mastectomies, breast re-excision rates** and/or **volume of excision from BCS** leading to **improved QoL.**

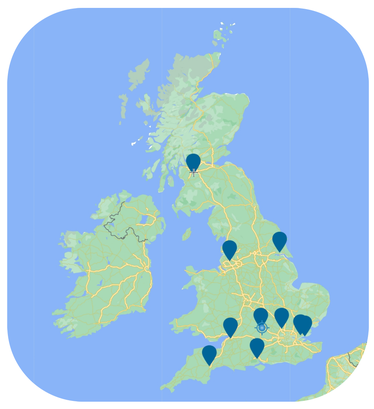
EndoNET Hospitals

TRIAL OPENS TO RECRUITMENT AT 10TH HOSPITAL!

Congratulations to NHS Lanarkshire who are the latest centre to open to recruitment.

They join 9 other UK hospitals who are already recruiting to the trial.

We have over 30 hospitals who have expressed an interest and we look forward to working with you in 2023.



UK hospitals open to recruitment

Recruitment

ENDONET RANDOMISES 9 PATIENTS!

Recruitment to EndoNET continues to build momentum. Congratulations to these 6 centres for randomising patients to the trial:

Hospital	Randomisations
St. Albans City Hospital	2
Royal Devon and Exeter	2
Basildon	2
Churchill	1
Southampton General	1
Southend	1

January 2023 was our best month of recruitment to date. Keep up the great work!

Top EndoNET Tips!

Here are some trial top tips:

1. Highlight patients who may be suitable for EndoNET during the MDT - screening can be done during MDT meetings!
2. QRI top tip - make sure **all of your team** and colleagues **are on board** with the study and it is **discussed at MDTs**!

Did you know we have an embedded Qualitative Recruitment Intervention (QRI)?

Lastest News

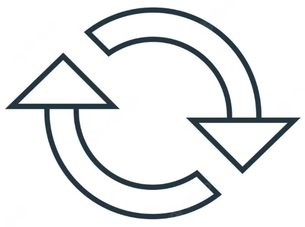
RCS Breast Surgical Trials Day

We attended the RCS Breast Surgical Trials day on Monday 16th January. It was great to meet research nurses, PIs and other surgical trial teams alike.

EndoNET colleagues at RCS Library in Holborn, London.

Amendment Submitted to Include T-stage 1 Tumours ≥ 15mm.

We have submitted an amendment to the regulatory authorities to include patients with T-stage 1 tumours ≥ 15mm.



Early analysis of screening data suggested that 40% of screened patients were ineligible due to tumours being <20mm or T-stage 4. We hope the approvals will be in place by March 2023!

Trial Looking for Additional Hospitals!

EndoNET is looking for additional hospitals to take part. If you are interested in joining the 30+ UK hospitals that will be recruiting, scan the QR code to find out more or contact us on: endonet@nds.ox.ac.uk.

Scan me:

Important Events for the Calendar

EndoNET Research Nurse Forum
Wednesday 15th February, 11.00-11.45 on Microsoft Teams.

EndoNET Investigator Meeting
Tuesday 14th March, 12.30-16.00 on Microsoft Teams.

We will be discussing your opinions on the trial and how we can optimise recruitment, with colleagues from the QRI team.

Sign up to our Investigator Meeting using the following QR code on the right.

Scan me:

Meet Our Patient Advocates

Patricia Fairbrother, Independent Cancer Patients Voice (ICPV)

Breast cancer survivor and patient advocate for breast cancer; ICPV Trustee.

Marcelle Bernstein, Independent

Breast cancer survivor and journalist/novelist. Keen interest in breast cancer clinical research.

The trial team wishes to thank our fantastic patient advocates for their continued input into the trial. We are very grateful for all your advice and support and reminding us the importance of patient and public involvement in all aspects of the trial.

Frequently Asked Questions!

Q: When should a participant start their endocrine treatment?
A: Participants should start their endocrine treatment (AIs: letrozole, anastrozole or exemestane) post-randomisation and within 7-days of entering the trial.

Q: Is EndoNET compatible with the POETIC-A study?
A: Yes. We have worked with the POETIC-A team to ensure that patients can enrol into both studies and we encourage you to do this if you can.

Q: A patient is eligible but we are planning breast conservation.
A: We are keen to recruit all eligible patients. The surgical primary endpoint is a comparison of mastectomy rates (proportion) between the two arms. Some patients planned for BCS require re-excision and some even go on to require mastectomy. We are also looking at other endpoints such as volume of excision and tumour size between the trial arms at surgery.

Q: **We don't do Ki67 analysis at our local site. Is this permitted? Do we get access to the Ki67 results?**
A: We are doing Ki67 analysis centrally at King's College London. You should provide us with the relevant tissue blocks/slides. Unfortunately we can't share the Ki67 results with you as these are for research and the results won't be available in real-time.

Q: What does the inclusion criterion 'Axillary N-01 on diagnostic USS +/- negative FNA or core biopsy' mean?
A: This means we include both node negative and node positive patients in the trial (as long as chemotherapy is unlikely at the point of screening).

Trans-EndoNET: Coming Soon!

We are thrilled to announce that we have secured funding from the NIHR Efficacy and Mechanism Evaluation (EME) Programme for a mechanistic sub-study called 'Trans-EndoNET'.

The sub-study will be integrated into the main study and is designed to assess the influence of patient metabolism on the response to NET in post-menopausal women with ER+ breast cancer.

The primary objective will be to determine whether there is an association between insulin resistance and antiproliferative response to aromatase inhibitors in early breast cancer.

We will provide you more information in the coming months!

Prof. Ramsey Cutress, Lead Investigator

Simon Lord, Chief Investigator

Funder, Sponsor and Key Affiliations

Funder: NIHR HTA Programme
Sponsor: University of Oxford
Trials Units: Surgical Interventions Trials Unit (NDS SITU) and Oxford Clinical Trials Research Unit (OCTRU).

Contact Us

Contact our trial inbox on endonet@nds.ox.ac.uk.

Follow us on Twitter @EndoNET_Trial for live trial updates and news.