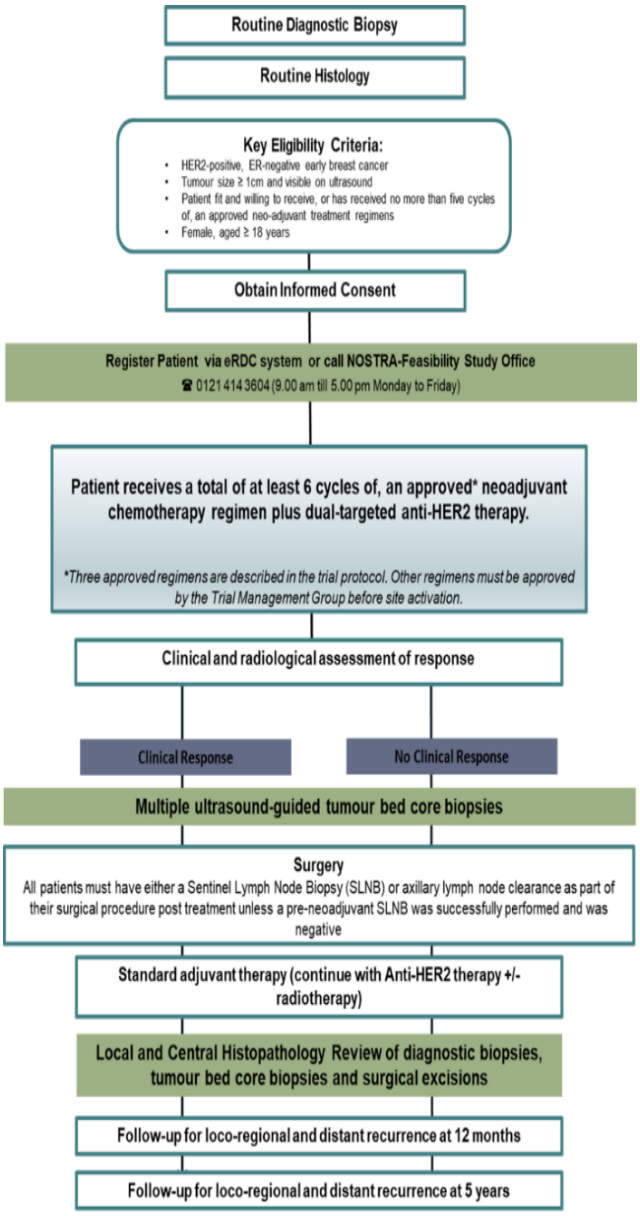
NOSTRA-Feasibility Study

A prospective non-randomised multicentre feasibility study to assess if patients with residual cancer following dual-targeted neoadjuvant chemotherapy treatment for HER2-positive, ER-negative early breast cancer can be identified by multiple image-guided tumour bed core biopsies

Study Design: A prospective non-randomised, single-arm, multicentre, feasibility study for a proposed future randomised phase III clinical trial. The NOSTRA-Feasibility Study opened its first site in May 2019 and recruited first patient in September 2019.



Primary Objective:

To determine whether patients with residual cancer can be identified by histological examination of multiple US-guided tumour bed core biopsies following dual-targeted neoadjuvant treatment for HER2-positive, ER-negative early primary breast cancer

Translational Research Objective:

To identify novel biomarkers with the ability to predict pathological Complete Response (pCR).

Patient Population:

150 Female patients with early invasive breast cancer that is HER2-positive and ER-negative and who are able to undergo neoadjuvant chemotherapy with dual-targeted anti-HER2 treatment and surgery.

Study Treatment:

Patients will receive at least six cycles of an approved neoadjuvant chemotherapy regimen, plus dual-targeted anti-HER2 treatment with pertuzumab and trastuzumab at the discretion of the treating clinician.

Key inclusion criteria:

-Adult female patient with histological diagnosis of operable HER2-positive, ER-negative, early stage invasive breast cancer.

-Tumour size ≥ 1cm and visible on US

-Patient fit and willing to receive, or is already receiving and has received no more than five cycles of, an approved treatment regimen

-Eastern Co-operative Group (ECOG) performance status of 0 or 1

-The radiology team are willing to perform the tumour bed biopsies

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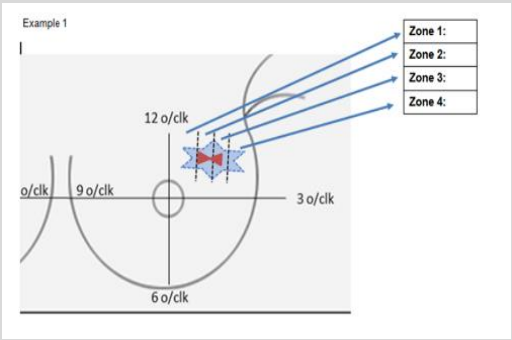
This is a simple study and is designed to align with standard of care. The only mandatory additional procedure is the taking of the tumour bed core biopsies. Shortly before surgery All other activities should be as standard of care for these patients. The study is suitable for all breast units with capacity to deliver standard neoadjuvant chemotherapy with dual targeted anti HER-2 directed therapy and access to freehand radiologically guided breast biopsy

The Tumour Bed Core Biopsies:

The only additional procedure in this study is the taking of tumour bed core biopsies. A fan of ultrasound-guided biopsies are taken in a routine outpatient setting after neoadjuvant treatment. Sites are reimbursed £160 per patient for the procedure and an additional £64 for these to be reported locally.



Other Study-related activity:

-Identifying, approaching and consenting eligible patients. This is ideally done at the beginning of neoadjuvant chemotherapy but can be later (up to cycle 5 out of 6) if necessary.

-Light data collection of chemotherapy delivered and surgery performed with basic follow up data (at 1 and 5 years). £342 per patient may be claimed for CRF completion.

-£250 per quarter may be claimed for site file set-up and maintenance.

- 'Top-up' pertuzumab can be provided to the hospital for individual patients where, for a variety of reasons, funding is not available through routine NHS pathways

Optional within the study:

ctDNA sub-study:

For consenting patients who have not yet commenced neoadjuvant chemotherapy, blood samples should be collected at three time points:

1. Prior to commencing neoadjuvant treatment
2. Post-cycle 1 of neoadjuvant treatment
3. After surgery (first visit to clinic post-surgery)

-These time points should coincide with routine blood tests taken within clinic.
-Sites are not required to process the blood samples.
-Blood tubes and packaging are provided and £15 per time point may be claimed.

MRI research:

Patients will be asked to consent to their MRI scans, taken as part of their standard care, to be collected retrospectively at the end of the study. Details of the collection and reimbursement processes will be available after a future protocol amendment.

Further information:
Please contact CRUK Clinical Trials Unit, University of Birmingham.
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