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A study to help understand the outcomes of pre-surgical treatment for breast cancer

Submission date 05/06/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 10/06/2019	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 01/03/2021	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

The use of treatment such as chemotherapy or hormonal therapy before surgery in women with early breast cancer has been shown to reduce the size of breast tumours, and potentially therefore reduce the amount of surgery required to treat these patients.

However, there appears to be variation in both how often these treatments are used across the UK, and in how decisions are made about surgery following treatment. The NeST study plans to carry out a national survey of practice, to see which patients are being treated with chemotherapy and hormone therapy before an operation. The study will look to see how patients are being followed up, to see if their breast cancer is getting smaller in response to treatment, and will see how many patients treated in this way in the UK have a cancer with disappears completely after treatment. We will also look to see how decisions are made about surgery after this treatment

Who can participate?

Participants in this study have been diagnosed with breast cancer and will be receiving standard treatment with medical therapy (either chemotherapy, endocrine therapy or targeted therapy)

What does the study involve?

The study is taking place in a number of breast units across the UK. It involves only the collection of anonymous information on women with breast cancer receiving standard treatment before surgery, and there is no change to treatment as a result of the study.

What are the possible benefits and risks of participating?

This study will provide information to guide future decision-making, and will allow us to ascertain best practice in this area

Where is the study run from?

Centre for Cancer Research & Cell Biology
Queen's University Belfast

When is the study starting and how long is it expected to run for?
The NeST Study will run from December 2017 for approximately 2 years, to allow data collection to be completed on all patients starting treatment between December 2017 and December 2018

Who is funding the study?
The study is funded by the Association of Breast Surgery.

Who is the main contact?
Mr Stuart McIntosh,
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Contact information

Type(s)
Public

Contact name
Mr Stuart McIntosh

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Neoadjuvant systemic therapy in breast cancer: a national prospective multicentre audit of neoadjuvant systemic therapy in breast cancer

Acronym
NeST

Study objectives
Neoadjuvant systemic therapies (NST) are increasingly used to treat breast cancer in the UK. However, there is a lack of high-quality data surrounding indications for use and access, short-term outcomes and surgical decision-making following NST. This study aims to document these with a view to establishing current UK practice in this area.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The NeST study does not require ethical approval because they involve the routine collection of clinical outcome data, and this has been agreed with host organisations.

Study design
Multi-centre prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Participants in this study have been diagnosed with breast cancer, and will be receiving standard treatment with medical therapy (either chemotherapy, endocrine therapy or targeted therapy). Data will be collected on baseline tumour characteristics and response to treatment.
Participants will then proceed to receive standard surgical treatment. Anonymised data will be collected on the operations performed, response to pre-operative treatment and surgical complications up to 30 days post-surgery. The duration of follow-up will vary according to the length of pre-surgical treatment but will be at least 6 months and should not be more than 12 months for any one patient.

Intervention Type
Drug

Phase

Not Applicable

Primary outcome measure
1. Investigate variation in practice in the use of neoadjuvant systemic therapy in the UK
Measurement – percentage of patients being treated with neoadjuvant chemotherapy and endocrine therapy and tumour molecular subtypes. Timepoint – baseline (at diagnosis).
2. Assess surgical practice following neoadjuvant therapy
Measurement – percentage of patients having mastectomy/breast conserving surgery.
Timepoint – after completion of neoadjuvant therapy
3. Determine pathological response rates after neoadjuvant therapy in current UK practice
Measurement – pathological complete response rate reported in all patients. Timepoint – after completion of neoadjuvant therapy.

Secondary outcome measures
1. Explore the stated indications for the use of neoadjuvant systemic therapy in the UK
Measurement – indications given by multidisciplinary team for choice of treatment. Timepoint – baseline
2. Examine treatment regimens in common use
Measurement – prescribed treatment regimens for neoadjuvant therapy. Timepoint – at commencement of standard therapy.
3. Investigate how response to neoadjuvant therapy for breast cancer is assessed and reported across the UK.
Measurement – number of patients having imaging during therapy. Timepoints – mid-treatment and at completion of treatment
4. Investigate surgical management of the axilla following neoadjuvant therapy
Measurement – percentage of patients have sentinel node biopsy and axillary node clearance before and after neoadjuvant therapy. Timepoints – at start of treatment and after completion of neoadjuvant treatment.

Overall study start date
01/12/2017

Completion date
30/11/2019

Eligibility

Key inclusion criteria
1. Age > 16 years
2. Histologically confirmed diagnosis of breast cancer
3. MDT recommended treatment of neoadjuvant systemic therapy (either hormonal or chemotherapy) - including patients entering into clinical trials of neoadjuvant systemic therapy.

Participant type(s)
Patient

Age group
Adult

Sex

Female

Target number of participants
1,000

Total final enrolment
1283

Key exclusion criteria
1. Patients entering “window of opportunity” clinical trials

Date of first enrolment
01/12/2017

Date of final enrolment
30/11/2018

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Belfast City Hospital
Lisburn Road
Belfast
United Kingdom
BT9 7AB

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Health Campus, Foresterhill Road
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre

Airedale NHS Foundation Trust
Skipton Road
Keighley
United Kingdom
BD20 6TD

Study participating centre
Betsi Calwaladr University Health Board
Ysbyty Gwynedd, Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary, Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Southmead Hospital Bristol
Southmead Road, Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
St Helens and Knowsley Teaching Hospitals
Burney Breast Unit, St Helens Hospital, Marshalls Cross Road
St Helens
United Kingdom
WA9 3DA

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrooke's Hospital, Cambridge Biomedical Campus, Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Birmingham City Hospital
Dudley Road
Birmingham
United Kingdom
B18 7QH

Study participating centre
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Glasgow Royal Infirmary
84 Castle Street
Glasgow
United Kingdom
G4 0SF

Study participating centre
Hampshire Hospitals NHS Foundation Trust
Royal Hampshire County Hospital, Romsey Road
Winchester
United Kingdom
SO22 5DG

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Mindelsohn Way, Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Homerton University Hospital
Homerton Row
London

United Kingdom
E9 6SR

Study participating centre
St James's Hospital
Beckett Street
Leeds
United Kingdom
LS8 7TF

Study participating centre
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP

Study participating centre
Wythenshawe Hospital
Southmoor Road, Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Milton Keynes University Hospital
Standing Way, Eagleston
Milton Keynes
United Kingdom
MK5 6LD

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Study participating centre

Ninewells Hospital
James Arrott Drive
Dundee
United Kingdom
DD2 1SY

Study participating centre
Altnagelvin Hospital
Glenshane Road
Londonderry
United Kingdom
BT47 6SB

Study participating centre
Nottingham University Hospitals NHS Trust - Breast Institute
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Queen Alexandra Hospital
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Royal Preston Hospital
Sharoe Green Lane, Fulton
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United Kingdom
PR2 9HT

Study participating centre
Royal Devon and Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Royal Marsen Hospital
Downs Road
Sutton
United Kingdom
SM2 5PT

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
Salisbury District Hospital
Odstock Road
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United Kingdom
SP2 8BJ

Study participating centre
Sheffield Teaching Hospitals NHS Trust
Royal Hallamshire Hospitals, Glossop Road

Sheffield
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S10 2JF

Study participating centre
Ulster Hospital Dundonald
Upper Newtonards Road, Dundonald
Belfast
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BT16 1RH

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Warrington and Halton Hospitals NHS Foundation Trust
Lovely Lane
Warrington
United Kingdom
WA6 1QG

Sponsor information

Organisation
Queen's University of Belfast

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United Kingdom
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researchgovernance@qub.ac.uk

Sponsor type
University/education

Website
http://qub.ac.uk

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Charity

Funder Name
Association of Breast Surgery

Results and Publications

Publication and dissemination plan
This protocol will be disseminated through the Mammary Fold Academic Research Collaborative (MFAC), the Reconstructive Surgery Trials Network, the Association of Breast Surgery, the British Association of Plastic, Reconstructive and Aesthetic Surgeons and others. Participating units will have access to their own data and information from individual units will be fed back with a comparison to the national data. National results will be fed back to the appropriate professional associations. Collective results will be analysed and the results presented at relevant scientific meetings and published in appropriate peer-reviewed journals. Results will also be made available to relevant patient advocacy groups such as Independent Cancer Patients' Voice. Thus, results will be available to aid in the decision-making for women considering NST.

Intention to publish date
01/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Stuart McIntosh (s.mcintosh@qub.ac.uk). De-identified raw participant level data (on baseline tumour characteristics, treatment regimens, and short-term outcomes) will be made available once the study is complete, the primary analysis has been carried out and the initial results published. Requests for access to the data will be reviewed by the NeST Study Steering Group prior to any data sharing.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/11/2019	06/01/2020	Yes	No