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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
05/06/2019		[X] Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
10/06/2019		Results		
Last Edited		Individual participant data		
01/03/2021	Cancer	[] 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, s.mcintosh@qub.ac.uk

## Contact information

#### Type(s)

Public

#### Contact name

Mr Stuart McIntosh

#### **ORCID ID**

https://orcid.org/0000-0002-4123-9611

#### Contact details

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## Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

#### 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

#### Study type(s)

Treatment

#### 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(s)

- 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.

#### Key secondary outcome(s))

- 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.

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Female

#### 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

**United Kingdom** 

England

Northern Ireland

Scotland

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

Study participating centre
Doncaster Royal Infirmary

Armthorpe Road

B18 7QH

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 Preston 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 Salisbury United Kingdom SP2 8BJ

# Study participating centre Sheffield Teaching Hospitals NHS Trust

Royal Hallamshire Hospitals, Glossop Road Sheffield United Kingdom S10 2JF

#### Study participating centre Ulster Hospital Dundonald

Upper Newtonards Road, Dundonald Belfast United Kingdom 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

#### **ROR**

https://ror.org/00hswnk62

# Funder(s)

#### Funder type

Charity

#### **Funder Name**

Association of Breast Surgery

### **Results and Publications**

#### 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes