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The use of a prognostic tool (EndoPredict®) to inform adjuvant chemotherapy decision in low to medium risk oestrogen receptor positive, Her--2 negative early breast cancer

Submission date 19/08/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 19/08/2015	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 23/05/2019	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English Summary
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-help-decide-if-women-with-breast-cancer-should-have-further-treatment-endopredict

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

19287

Study information

Scientific Title
The use of a prognostic tool (EndoPredict®) to inform adjuvant chemotherapy decision in low to medium risk oestrogen receptor positive, Her--2 negative early breast cancer: feasibility, acceptability and economic impact in multicentre UK NHS practice

Acronym
EndoPredict

Study hypothesis
Breast cancer is common and causes a large burden of suffering. The majority of women with breast cancer are ER positive, HER2 negative. Currently, a number of factors are used to stratify patients as being either high risk or low risk for distant metastases developing within 10 years of surgery. If patients fall within the low risk group, they are treated with endocrine therapy and if they are highrisk, they are treated with endocrine therapy and chemotherapy. Patients who fall into the intermediate risk category present a challenge to clinicians and in many cases where there is uncertainty, chemotherapy may be used as a precautionary measure, resulting in possible overuse of chemotherapy in patients. Chemotherapy has a significant side effect profile and it is both resource intensive and high cost. EndoPredict is a multigene test for predicting likelihood of distant metastases in patients with ER positive, HER2-negative breast cancer. The tool combines gene expression and tumour prognostic indicators to identify a subgroup of women who have low risk of distant recurrence of disease. This information can therefore help clinicians identify women who would not benefit from chemotherapy and save them the unnecessary side effects of treatment. This trial will take place in high patient volume NHS breast oncology clinics in South-East England. The study will look at the impact of the EndoPredict tool on clinical decision making by doctors, by comparing chemotherapy decisions before and after information from the EndoPredict is added. It also aims to explore patient attitudes surrounding risk and satisfaction when it is used. Cost analysis will be performed to assess if there is longer term financial benefit with its use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford C, 07/04/2015, ref: 15/SC/0090

Study design
Non-randomised; Interventional; Design type: Diagnosis, Treatment

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Condition
Topic: Cancer; Subtopic: Breast Cancer; Disease: Breast

Interventions
Eligible patients will be discussed post-operatively in the relevant local breast multidisciplinary meeting. Those who are identified as eligible will ideally be given the patient information sheet by a member of the breast team at the post-surgical review, or sent a covering letter and patient information sheet in the post prior to first oncology consultation., or given the patient information sheet by a member of the breast team at the post-surgical review. If they give their consent to the study, their breast surgery tissue will be sent to a central lab to undergo the EndoPredict test. At the first consultation, patients will be invited to complete the 3 following questionnaires: (Decision conflict scale (DCS) and the STAI trait/state anxiety). Patient and oncologist meet again within 2 weeks with EndoPredict test results available. Additional information from this test is shared and discussed and a joint treatment decision made about adjuvant chemotherapy. Patients then complete questionnaires (Decision conflict scale (DCS) and the STAI state form. Decision and chemotherapy regimen is documented in CRF.

Intervention Type
Other

Primary outcome measure
Change in use of chemotherapy, measuring any change in treatment decision after receiving the EndoPredict test results, by the patient and by the clinician, recorded on a case report form.

Secondary outcome measures
Recording psychosocial outcomes which may influence decision making, recorded on STAI trait, STAI state, and DCS licensed questionnaires. Economic analysis of difference in chemotherapy use.

Overall study start date
21/07/2015

Overall study end date
27/10/2016

Eligibility

Participant inclusion criteria
1. Women over 18 years of age with first presentation of early Oestrogen Receptor +ve and HER-2
2. Negative breast cancer with all known disease surgically removed
3. Women who have an unclear decision regarding chemotherapy based on standard prognostic criteria

4. Performance status and general health sufficient in the judgement of the treating oncologist to manage adjuvant chemotherapy
5. Ability to understand verbal and written English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 151; UK Sample Size: 151

Total final enrolment
149

Participant exclusion criteria
1. Patients unwilling to accept adjuvant chemotherapy
2. Patients unable to give full informed consent

Recruitment start date
28/07/2015

Recruitment end date
01/05/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Sussex County Hospital (lead centre)
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre

Western Sussex Hospitals NHS Foundation Trust
Lyndhurst Rd
Worthing, West Sussex
United Kingdom
BN11 2DH

Study participating centre
Surrey & Sussex Healthcare NHS
East Surrey Hospital
Canada Ave
Redhill
Surrey
United Kingdom
RH1 5RH

Study participating centre
Dartford and Gravesham NHS Trust
Darent Valley Hospital
Darenth Wood Road
Dartford
Kent
United Kingdom
DA2 8DA

Study participating centre
East Sussex Healthcare NHS Trust
King's Dr
Eastbourne
East Sussex
United Kingdom
BN21 2UD

Study participating centre
Maidstone & Tunbridge Wells NHS Trust
Tunbridge Wells Hospital
Tonbridge Road
Tunbridge Wells
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United Kingdom
TN2 4QJ

Study participating centre
East Kent Hospitals University NHS Foundation Trust
Kent
United Kingdom
CT1 3NG

Study participating centre
Frimley Park Hospital
Portsmouth Road
Frimley
Surrey
United Kingdom
GU16 7UJ

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

Sponsor information

Organisation
Brighton & Sussex University Hospitals NHS Trust

Sponsor details
CIRU, Royal Sussex County Hospital
Eastern Road
Brighton
England
United Kingdom
BN2 5BE

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type

Industry

Funder Name
Myriad Genetics Inc

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results			23/05/2019	No	Yes
HRA research summary			28/06/2023	No	No