

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 23/05/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<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

Contact name

Mrs Amy Arbon

Contact details

Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Additional identifiers

Protocol serial number

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 objectives

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

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(s)

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.

Key secondary outcome(s)

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.

Completion date

27/10/2016

Eligibility

Key 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Total final enrolment

149

Key exclusion criteria

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

Date of first enrolment

28/07/2015

Date of final enrolment

01/05/2016

Locations**Countries of recruitment**

United Kingdom

England

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
Darent 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
Kent
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

Funder(s)

Funder type

Industry

Funder Name

Myriad Genetics Inc

Results and Publications

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?
HRA research summary			28/06/2023	No	No
Plain English results			23/05/2019	No	Yes