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A double-blind short-term presurgical study to assess the molecular predictors of the antiproliferative effects of lapatinib in women with primary breast cancer

Submission date
28/07/2006

Recruitment status
No longer recruiting

Registration date
12/09/2006

Overall study status
Completed

Last Edited
04/05/2016

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00299286

Secondary identifying numbers

N/A

Study information

Scientific Title
A double-blind short-term presurgical study to assess the molecular predictors of the antiproliferative effects of lapatinib in women with primary breast cancer

Acronym
MAPLE

Study objectives
To assess changes in Ki67 and molecular markers following a short pre-surgical course of lapatinib.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending as of 12/09/2006

Study design
Randomised double-blind/placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
Lapatinib versus placebo in a ratio of 3:1.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Lapatinib

Primary outcome measure
Changes in Ki67 after short term treatment with lapatinib

Secondary outcome measures
Assess how changes in Ki67 and apoptosis relate to molecular markers at baseline and after two weeks

Overall study start date
01/10/2006

Completion date
01/10/2007

Eligibility

Key inclusion criteria
1. All female patients under 80 years of age who present with a breast lump
2. Have a histological diagnosis of breast cancer on biopsy
3. Are scheduled for primary surgery
4. Have an Eastern Cooperative Oncology Group (ECOG) performance status of zero to two
5. Have a cardiac ejection fraction within the normal range as measured by echocardiogram (ECG)
6. Have an adequate bone marrow function, serum creatine and bilirubin with normal limits
7. Are able to swallow and retain oral medication
8. Have given written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
120

Key exclusion criteria
1. Prior malignancy
2. Evidence of metastatic disease
3. Use of hormonal therapy within four weeks
4. Receiving other investigational agents
5. Systemic steroid therapy
6. Uncontrolled inter-current illness including significant ECG abnormality

Date of first enrolment
01/10/2006

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Marsden Hospital
London
United Kingdom
SW3 6JJ

Sponsor information

Organisation
Royal Marsden Hospital and the Institute of Cancer Research (UK)

Sponsor details
Royal Marsden Hospital
Fulham Road
London
England
United Kingdom
SW3 6JJ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/034vb5t35

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

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?
Results article	results	01/07/2015		Yes	No