

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/05/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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United Kingdom
SW3 6JJ

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