

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

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>28/07/2006   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>12/09/2006 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>27/11/2025       | <b>Condition category</b><br>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

Prof Stephen Johnston

### Contact details

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Fulham Road  
London  
United Kingdom  
SW3 6JJ

## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT00299286

### Protocol serial number

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

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Breast cancer

**Interventions**

Lapatinib versus placebo in a ratio of 3:1.

Added 27/11/2025:

Additional Data Linkage Information:

Participants from this trial will also be included in the INTERACT project which will link to their data held by NHS England. For more information, please see the INTERACT website:

<https://www.icr.ac.uk/interact>.

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Lapatinib

**Primary outcome(s)**

Changes in Ki67 after short term treatment with lapatinib

**Key secondary outcome(s)**

Assess how changes in Ki67 and apoptosis relate to molecular markers at baseline and after 2 weeks

**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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

80 years

**Sex**

Female

**Total final enrolment**

0

**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**

United Kingdom

England

**Study participating centre**

Royal Marsden Hospital

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London

England

SW3 6JJ

**Sponsor information****Organisation**

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

**ROR**

<https://ror.org/034vb5t35>

**Funder(s)****Funder type**

Industry

**Funder Name**

GlaxoSmithKline

**Alternative Name(s)**

GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/07/2015   |            | Yes            | No              |