# 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	Recruitment status No longer recruiting	[X] Prospectively registered	
28/07/2006		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
12/09/2006	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
27/11/2025	Cancer		

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Stephen Johnston

#### Contact details

Royal Marsden Hospital 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?
Results article	results	01/07/2015	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	i No	Yes