

# LaMB - maintenance lapatinib versus placebo after first-line chemotherapy in patients with locally advanced or metastatic bladder cancer

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|--------------------------|-----------------------------|--|
| <b>Submission date</b>   | <b>Recruitment status</b>   | <input type="checkbox"/> Prospectively registered    |
| 31/03/2010               | No longer recruiting        | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b> | <b>Overall study status</b> | <input type="checkbox"/> Statistical analysis plan   |
| 31/03/2010               | Completed                   | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b>       | <b>Condition category</b>   | <input type="checkbox"/> Individual participant data |
| 04/04/2022               | Cancer                      |  |

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-lapatinib-for-people-with-bladder-cancer-that-has-spread>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2007-001826-28

### ClinicalTrials.gov (NCT)

NCT00949455

### Protocol serial number

5660

# Study information

## Scientific Title

A phase II/III, randomised, two-arm comparison of maintenance lapatinib versus placebo after first-line chemotherapy in patients with HER1 and/or HER2 overexpressing locally advanced or metastatic bladder cancer

## Acronym

LaMB

## Study objectives

Metastatic bladder cancer is treated with platinum analogue based chemotherapy. In this study patients will initially be treated with standard chemotherapy for locally advanced and metastatic bladder cancer. Those patients who have either a response to treatment (Response Evaluation Criteria in Solid Tumours [RECIST] criteria) or stabilisation of disease will go onto the study. Only those patients who are HER1 and/or HER2 positive will be eligible, as previous studies have shown that these individuals are most likely to respond to treatment with lapatinib. Patients will be randomised to receive maintenance therapy with either lapatinib or placebo. Therapy will continue until disease progression, excessive toxicity or patient request, at which point the treatment will be stopped and patients will be treated according to the doctor's discretion.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

South East Research Ethics Committee, 28/11/2007, ref: 07/H1102/73

## Study design

Randomised multicentre double-blinded trial

## Primary study design

Interventional

## Study type(s)

Treatment

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

Topic: National Cancer Research Network; Subtopic: Bladder Cancer; Disease: Bladder (advanced)

## Interventions

1. Lapatinib
2. Placebo

Dosage given = 1500 mg (6 x 250 mg tablets) per day. Patients will receive treatment until progression of disease. Follow up is continued at doctor's discretion until death.

## Intervention Type

Drug

**Phase**

Phase II/III

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

Lapatinib

**Primary outcome(s)**

Compare progression-free survival (PFS) in patients with HER1 and/or HER2 over expressing stage IV b, measured after the last follow up of the last patient.

**Key secondary outcome(s)**

Measured after the last follow up of the last patient:

1. To compare overall survival (OS) between the two groups
2. Evaluate the safety and tolerability

**Completion date**

01/06/2011

## Eligibility

**Key inclusion criteria**

1. Histologically confirmed metastatic or locally advanced stage IV transitional cell carcinoma of the urothelium
2. Able to commence study drug 3 - 8 weeks after completion of 1st line chemotherapy for metastatic bladder cancer
3. HER1 and/or HER 2 positive, confirmed by central lab
4. Objective response or stable disease following 4 - 8 cycles of first-line chemotherapy
5. Eastern Cooperative Oncology Group (ECOG) performance status 0 - 3
6. Left ventricular ejection fraction (LVEF) within normal range as measured by ECHO or MUGA
7. Written informed consent
8. Aged over 18 years, either sex

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

232

## **Key exclusion criteria**

1. Progression with first-line chemotherapy for metastatic disease
2. Previous anti-HER1 or HER2 therapy
3. More than one line of chemotherapy for metastatic or locally advanced disease
4. Significant cardiac disease
5. Patients receiving less than 4 or more than 8 cycles of chemotherapy before randomisation
6. Major surgery or curative radiotherapy after chemotherapy (palliative radiotherapy is allowed)

## **Date of first enrolment**

31/10/2008

## **Date of final enrolment**

01/06/2011

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

**ECMC, Barts and the London School of Medicine and Dentistry**

London

United Kingdom

EC1M 6BQ

## **Sponsor information**

### **Organisation**

Queen Mary, University of London (UK)

### **ROR**

<https://ror.org/026zzn846>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

GlaxoSmithKline (UK)

**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**

Not provided at time of registration

**IPD sharing plan summary****Study outputs**

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               | results                       | 01/06/2015   |            | Yes            | No              |
| <a href="#">Results article</a>               | results                       | 01/01/2017   |            | Yes            | No              |
| <a href="#">Basic results</a>                 |                               |              | 20/05/2019 | No             | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |
| <a href="#">Plain English results</a>         |                               |              | 04/04/2022 | No             | Yes             |