

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

Submission date 31/03/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 31/03/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/04/2022	Condition category Cancer	☐ Individual participant data

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

ClinicalTrials.gov (NCT)

NCT00949455

Clinical Trials Information System (CTIS)

2007-001826-28

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

Primary study design

Interventional

Study design

Randomised multicentre double-blinded trial

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?
Results article	results	01/06/2015		Yes	No
Results article	results	01/01/2017		Yes	No
Basic results			20/05/2019	No	No
Plain English results			04/04/2022	No	Yes