ISRCTN35418671 https://doi.org/10.1186/ISRCTN35418671

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 [X] 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
Ms Charlotte Rofe

Contact details
ECMC, Barts and the London School of Medicine and Dentistry
Old Anatomy Building
Charterhouse Square
London
United Kingdom
EC1M 6BQ

Additional identifiers

EudraCT/CTIS number
2007-001826-28

IRAS number

ClinicalTrials.gov number
NCT00949455

Secondary identifying numbers
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

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

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 measure
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.

Secondary outcome measures
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

Overall study start date
31/10/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 204

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
England

United Kingdom

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)

Sponsor details
5 Walden Street
Whitechapel
London
England
United Kingdom
E1 2EF

Sponsor type
University/education

Website
http://www.qmul.ac.uk/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline (UK)

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
Not provided at time of registration

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	01/06/2015		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