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A study of lapatinib in combination with oxaliplatin and capecitabine in oesophageal and gastric cancers

Submission date 27/05/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 27/05/2011	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 25/10/2022	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-lapatinib-with-chemotherapy-for-cancer-of-the-food-pipe-and-stomach-leo

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2010-019602-16

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

9848

Study information

Scientific Title
A study of Lapatinib in combination with oxaliplatin and capecitabine in Early HER-2 overexpressing Oesophageal and gastric cancers

Acronym
LEO

Study objectives
This study will test whether the ex vivo molecular response on a pre-treatment biopsy can predict the molecular response on a biopsy taken after 10 days of treatment with lapatinib. The study will also report observations of patterns of radiological, functional imaging and pathological response associated with molecular response

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West 3 REC, 26/10/2010, 10/H0106/73

Study design
Non-randomised, interventional, observational qualitative trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Upper Gastro-Intestinal Cancer; Oesophagus, Stomach

Interventions
1. All 25 patients will be treated with lapatinib, there is no control arm
2. Fresh biopsies will be taken prior to lapatinib treatment start and 10 days post treatment start
3. All patients will have blood tests and renal function assessment prior to study entry and then after 31, 52 and 72 days of treatment
4. Treatment with lapatinib, oxaliplatin and capecitabine

5. All patients have a CT scan of thorax and abdomen prior to therapy and then another one after 3 cycles of chemotherapy for tumour assessmnet
6. All patient undergo a baseline whole body FDG-PET/CT examination at study entry and then 10 days after start of lapatinib therapy
7. Follow up length: 24 month(s)
8. Study entry : registration only

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
1. Molecular response
2. Timepoint(s): 10 days post treatment with lapatinib

Secondary outcome measures
1. FDG PET response timepoint(s): 10 days post treatment with lapatinib
2. Objective radiological response timepoint(s): 72 days post treatment
3. Pathological complete response timepoint(s): 102 days post treatment

Overall study start date
31/03/2010

Completion date
31/07/2015

Eligibility

Key inclusion criteria
1. Histologically confirmed gastric or oesophageal adenocarcinoma
2. Human Epidermal growth factor Receptor 2 (HER-2) 3+ on IHC OR HER-2 2+ on IHC but shown to have HER-2 amplification by (Fluorescent In-Situ Hybridization) FISH
3. Decision to treat with curative intent
4. Deemed to require chemotherapy prior to surgery using standard management algorithms
5. Ability to swallow oral medication
6. Baseline 18FDG PET/CT scan showing no evidence of distant metastases
7. Adequate haematological parameters: ANC = 1.0 x 109/L; WBC = 3.0 x 109/L; Plt = 100 x 109/L; haemoglobin (Hb) = 9g/dL (can be post-transfusion)
8. Adequate renal function (Measured or calculated creatinine clearance = 60 ml/min- if calculated the Cockcroft-Gault equation (Appendix A) to be used
9. Adequate liver function: serum Bilirubin = 1.5 x ULN; ALT/AST = 1.5 x ULN; ALP = 2.5 x ULN
10. Age >18 years
11. Women of child bearing potential using medically approved contraception (Postmenopausal women must have been amenorrheic for at least 12 months to be considered of non-childbearing potential)
12. Male patients using barrier contraceptives during the trial and for 6 months after the completion of the trial
13. Target gender: male & female
14. Lower age limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 25

Total final enrolment
10

Key exclusion criteria
1. Advanced disease not amenable to surgery
2. Previous diagnosis of malignancy (excluding adequately treated Cervical carcinoma in situ or Basal cell carcinoma of the skin)
3. Abnormal Cardiac function (LVEF below normal as measured by echocardiogram or MUGA scan)
4. History of clinically significant cardiac disease e.g. symptomatic coronary artery disease, uncontrolled cardiac dysrhythmia or myocardial infarction within the last 12 months)
5. History of interstitial lung disease (e.g., pneumonitis or pulmonary fibrosis) or evidence of interstitial lung disease on baseline chest CT scan
6. Known peripheral neuropathy >Grade 1 (absence of deep tendon reflexes as the sole neurological abnormality does not render the patient ineligible)
7. Inability to give informed consent
8. Hypersensitivity to lapatinib or oxaliplatin or capecitabine
9. Prior treatment with chemotherapy or lapatinib or other specific anticancer therapy
10. Squamous cell carcinomas, unclear differentiation type, sarcomas, carcinoid or GIST
11. Known positive tests for human immunodeficiency virus (HIV) infection, hepatitis C virus, acute or chronic active hepatitis B infection
12. Pregnancy/breastfeeding
13. Subjects who have current active hepatic or biliary disease (with exception of patients with Gilbert's syndrome, asymptomatic gallstones, liver metastases or stable chronic liver disease per investigator assessment)
14. Treatment with another investigational agent within 30 days of commencing study treatment
15. Known or suspected dihydropyrimidine dehydrogenase deficiency (DPD)
16. Galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption

Date of first enrolment
17/06/2011

Date of final enrolment
16/10/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
University College London Hospital
235 Euston Road
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Addenbrookes Hospital
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

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
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan
The protocol has not specified these data sharing requirements, and patients have not consented to data sharing (recruited from 2011–2013) therefore this is not applicable. The trial is currently in the process of being archived.

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	03/11/2015		Yes	No
Plain English results			25/10/2022	No	Yes
HRA research summary			28/06/2023	No	No