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

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

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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2010-019602-16

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 assessment
- 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 = $1.0 \times 109/L$; WBC = $3.0 \times 109/L$; Plt = $100 \times 109/L$; 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 = $1.5 \times ULN$; ALT/AST = $1.5 \times ULN$; ALP = $2.5 \times ULN$; 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 Hills Road Cambridge England United Kingdom CB2 0QQ

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 |