

Phase III randomised, double-blind, placebo-controlled trial of Gefitinib (Iressa®) versus placebo in Oesophageal Cancer progressing after chemotherapy

Submission date 25/09/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/11/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-trial-looking-at-gefitinib-for-people-with-advanced-cancer-of-the-foodpipe-cog-trial>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2007-005391-13

ClinicalTrials.gov (NCT)

NCT01243398

Protocol serial number

OCTO_005

Study information

Scientific Title

Phase III randomised, double-blind, placebo-controlled trial of Gefitinib (Iressa®) versus placebo in Oesophageal Cancer progressing after chemotherapy

Acronym

COG

Study objectives

That gefitinib (Iressa®) 500 mg once daily will halt/slow the progression of oesophageal adenocarcinoma and squamous cancers, and thereby improve the survival of patients with these cancers.

As of 15/02/2011 the anticipated end date for this trial has been updated from 01/09/2010 to 30/09/2011.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 26/10/09: Multicentre Research Ethics Committee (MREC) approved 20/10/2008

Study design

National multi-centre phase III randomised double-blind placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Oesophageal cancer

Interventions

450 (225 per arm) patients will be randomised to either Gefitinib 500 mg (Iressa®) or placebo. As of October 2009: recruiting

Duration of the interventions: The trial will close 6 months after the end of recruitment or when 389 events have occurred.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Gefitinib (Iressa®)

Primary outcome(s)

Overall survival, assessed at each visit (every 4 weeks) or in-between if death is reported to site by family/friends until the end of trial.

Key secondary outcome(s)

1. Toxicity of gefitinib monotherapy in oesophageal cancer patients, assessed through Adverse Events (AE) and Serious Adverse Events (SAE) reporting (assessed at each visit or in between when reported by patients/family)
2. Quality of life, assessed using the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 and the EORTC QLQ-OES18 at baseline, 4 weeks, 8 weeks and 12 weeks
3. Time to clinical or radiological progression, assessed by the following:
 - 3.1. Examination by medical staff at each visit
 - 3.2. CT Scans (chest and abdomen) at baseline, 4, 8 and 16 weeks and then every 8 weeks until the end of trial
 - 3.3. Chest X-rays at baseline, 4, 8, 12 and 16 weeks and then every 8 weeks until the end of trial
4. Identification of genetic signature associated with benefit, via blood samples and tissue taken at biopsy using Deoxyribonucleic Acid (DNA) microarray technology to identify genes associated with response and prognosis. Please note that this will be done by HANDEL (a translational research project) which will run in parallel to the COG Trial as a separate protocol

Completion date

30/09/2011

Eligibility

Key inclusion criteria

Prior to 26/10/09:

1. Aged greater than 18 years
2. Adenocarcinoma, squamous cell cancer or poorly differentiated cancer for Type I and Type II oesophageal cancer. NB: Patients with epithelial tumours of the oesophagus are eligible
3. Up to two prior regimens, either one as neoadjuvant plus one for advanced disease, or up to two for advanced disease
4. Creatinine clearance greater than 30 ml/min; alkaline phosphatase, bilirubin and Alanine aminotransferase (ALT) less than 2 x Upper Limit of Normal (ULN); haemoglobin greater than 10 g/dL
5. World Health Organization (WHO) performance Status 0, 1 or 2
6. Measurable or evaluable disease by Computerised Tomography (CT) scan
7. Able to swallow tablets

8. Patients with brain metastases must be stable and have received cranial irradiation prior to entry

9. Patients must complete the Quality Of Life (QOL) baseline questionnaire

Amended 26/10/09:

1. Aged greater than 18 years

2. Adenocarcinoma, squamous cell cancer or poorly differentiated cancer for Type I and Type II oesophageal cancer. NB: Patients with epithelial tumours of the oesophagus are eligible

3. Histologically proven adenocarcinoma, squamous cell cancer or poorly differentiated epithelial malignancy

4. Up to two prior regimens, either one as neoadjuvant plus one for advanced disease, or up to two for advanced disease [date of last administration of chemotherapy must be >6 weeks prior to randomisation]

5. World Health Organization (WHO) performance Status 0, 1 or 2

6. Measurable or evaluable disease by Computerised Tomography (CT) scan

7. Able to swallow tablets

8. Patients with brain metastases must be stable and have received cranial irradiation prior to entry

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Prior to 26/11/09:

1. Previous malignancy not treated curatively

2. Previous malignancy treated curatively less than 5 years ago

3. Medical condition considered to interfere with the safe participation in the trial

4. Radiotherapy to site of measurable or evaluable disease in the last month

5. Pregnancy

6. Not able to give written informed consent

Amended 26/10/09:

1. Presence of previous or other malignancy likely to confound results or interfere with gefitinib therapy

2. Medical condition considered to interfere with the safe participation in the trial

3. Radiotherapy to site of measurable or evaluable disease in the last 4 weeks

4. Pregnancy

5. Sexually active patients of child-bearing potential not using adequate contraception* (male and female) [post menopausal women must have been amenorrhoeic for at least 12 months to be

considered as having non-child-bearing potential]

6. Serum bilirubin greater than 3 times the upper limit of reference range (ULRR)

7. Aspartate aminotransferase (AST/SGOT) or alanine aminotransferase (ALT/SGPT) $\geq 2.5 \times \text{ULN}$ if no demonstrable liver metastases (or $>5 \times$ in presence of liver metastases)

8. Any evidence of clinically active Interstitial Lung Disease (ILD) (patients with chronic, stable, radiographic changes who are asymptomatic need not be excluded)

9. Known severe hypersensitivity to gefitinib or any of the excipients of this product

10. On other cytotoxic chemotherapy, immunotherapy, hormonal therapy (excluding contraceptives and replacement steroids) or experimental medications

* For female trial participants: birth control pills, approved contraceptive implant, spermicidal foam and condoms, intrauterine device, or prior tubal ligation. For male trial participants: condoms and spermicidal foams or prior vasectomy.

Date of first enrolment

01/03/2009

Date of final enrolment

30/09/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

COG Trial Co-ordinator

Oxford

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OX3 7DQ

Sponsor information

Organisation

University of Oxford (UK)

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (UK) - main funding

Funder Name

Astra Zeneca (UK) - Supplying trial medication (Gefitinib) and placebo

Results and Publications

Individual participant data (IPD) sharing plan

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	01/07/2014		Yes	No
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes