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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

Registration date
14/11/2007

Overall study status
Completed

Last Edited
26/10/2018

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Study website
http://www.octo-oxford.org.uk/alltrials/trials/COG.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2007-005391-13

IRAS number

ClinicalTrials.gov number
NCT01243398

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/03/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
450

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 26/101/09:
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 amenorrheic 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) ≥ 2.5 x ULN if no demonstrable liver metastases (or >5 x 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
England

United Kingdom

Study participating centre
COG Trial Co-ordinator
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Sponsor information

Organisation
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Sponsor type
University/education

Website
http://www.ox.ac.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Plain English results				No	Yes
Results article	results	01/07/2014		Yes	No