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TRANSlational Cancer Oesophagus Gefitinib study (TRANS-COG)

Submission date
09/11/2011

Recruitment status
No longer recruiting

Registration date
05/03/2012

Overall study status
Completed

Last Edited
12/12/2017

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Oesophagogastric cancer refers to cancer of the stomach or oesophagus (also known as the gullet or food pipe). The COG study aimed to compare the effectiveness of an experimental drug called Gefitinib with placebo (dummy) tablets in patients with advanced oesophagogastric cancer. Gefitinib works by blocking an important receptor on the surface of cancer cells called the Epidermal Growth Factor Receptor or EGFR. It has been shown in lung cancer that patients whose tumours have mutations in the gene for EGFR respond very well to Gefitinib treatment. Gefitinib has been shown to be of benefit in some other types of cancer and tumour shrinkage has been demonstrated in some small studies of patients with oesophageal cancer treated with gefitinib. In the TRANSCOG study we are planning to analyse tumour samples for EGFR gene and other similar gene mutations to find out whether their presence in oesophageal cancers can predict which patients will respond and benefit from Gefitinib treatment and which will not. If this is possible we will be able to develop tests to allow us to target treatment to those patients most likely to respond and benefit from this treatment, and in those patients who are unlikely to respond we can avoid using a treatment that will not work and potentially try other treatments which may have a better chance of success.

Who can participate?
Oesophagogastric cancer patients aged over 18 who participated in the COG study.

What does the study involve?
Partcipants will be asked to sign a consent form to allow us to analyse a sample of their tumour tissue that has already been obtained during previous endoscopy and biopsy of your cancer or at the time of previous surgery. Participants will not need to undergo any extra tests, treatments or procedures to participate in the TRANSCOG study.

What are the possible benefits and risks of participating?
At this early point in the research it is very unlikely that the TRANSCOG trial will benefit participants directly, but by taking part in this study researchers will find out more about genetic mutations that cause cancer and mutations which cause tumours to respond (or not respond) to treatment. As the rate of oesophageal cancer is increasing, the gift of providing tumour samples is invaluable to the progression of cancer research. Please note that the analysis performed is a

genetic analysis of the tumour and not a genetic analysis of each participant. Consequently, the results will have no implications regarding why participants developed the cancer, or for any of their family members. No extra tests, treatments or procedures are required for participation in TRANSCOG, as the tumour specimens used are those which are 'left over' from previous procedures.

Where is the study run from?
Section of Translational Medicine, Division of Applied Medicine at the University of Aberdeen (UK).

When is the study starting and how long is it expected to run for?
October 2011 to December 2012.

Who is funding the study?
Project Grant from the Experimental and Translational Research Committee - Scottish Government Chief Scientist's Office, NHS Grampian Endowments and Grampian Gastro-oesophageal Cancer Research Fund (GASTROCAN).

Who is the main contact?
Dr Asa Dahle-Smith
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10623

Study information

Scientific Title
Qualification of predictive biomarkers for epidermal growth factor receptor tyrosine kinase inhibitor therapy in oesophagogastric adenocarcinoma

Acronym
TRANS-COG

Study objectives
TRANS-COG is a translational study involving molecular analysis of tumour samples from patients enrolled in the Cancer Oesophagus Gefitinib (COG) trial (EudraCT: 2007-005391-13, ISRCTN29580179) to identify the predictive and prognostic impact of epidermal growth factor receptor (EGFR) signalling pathway abnormalities and determine their clinical utility as biomarkers to optimise clinical and cost effectiveness of tyrosine-kinase inhibitor (TKI) therapy in oesophagogastric cancer. Mutation analysis of EGFR, KRAS, BRAF and phosphoinositide-3-kinase, catalytic, alpha polypeptide (PIK3CA) will be performed and EGFR gene copy number determined by fluorescent in-situ hybridisation (FISH). A tissue microarray of trial tumours will be constructed and, Immunohistochemistry (IHC) for EGFR and p-AKT performed.

More details can be found at http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=10623

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Committee, 08/08/2011, ref: 11/AL/0372

Study design
Observational clinical study

Primary study design
Observational

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Upper Gastro-Intestinal Cancer

Interventions
EGFR pathway analysis

Mutational analysis of EGFR, KRAS, BRAF and PIK3CA and EGFR FISH

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Overall survival in different biomarker groups

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/09/2011

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Patients with oesophagogastric cancer must be eligible for and enrolled in the COG trial
2. Ability to provide written informed consent
3. Formalin-fixed and paraffin-embedded (FFPE) tumour material available
4. Male and female participants
5. Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 300; UK Sample Size: 300

Key exclusion criteria

1. Patients not enrolled in COG trial
2. Inability to provide written informed consent
3. No FFPE tumour material available for analysis

Date of first enrolment
01/09/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Aberdeen
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
Health Services Research Unit
Polwarth Building
Foresterhill
Aberdeen
Scotland
United Kingdom
AB25 2ZD

Sponsor type
University/education

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

ROR

https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Scottish Government, Department of Health (UK)

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