

TRANSlational Cancer Oesophagus Gefitinib study (TRANS-COG)

Submission date 09/11/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 05/03/2012	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 12/12/2017	Condition category Cancer	☐ 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?

Participants 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

asadahle-smith@nhs.net

Contact information

Type(s)

Scientific

Contact name

Dr Asa Dahle-Smith

Contact details

University of Aberdeen

Polwarth Building

Foresterhill

Aberdeen

United Kingdom

AB25 2ZD

-

asadahle-smith@nhs.net

Additional identifiers

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

Overall survival in different biomarker groups

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

Scotland

Study participating centre

University of Aberdeen

Aberdeen

United Kingdom
AB25 2ZD

Sponsor information

Organisation

University of Aberdeen (UK)

ROR

<https://ror.org/016476m91>

Funder(s)

Funder type

Government

Funder Name

Scottish Government, Department of Health (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration