

Clinical trial to identify biomarkers to select patients with esophageal cancer for oxaliplatin and 5-fluorouracil chemotherapy prior to surgery

Submission date 03/10/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/10/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/08/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

At present, patients with cancer of the gullet (food pipe) are offered chemotherapy treatment before surgery, but there is no way of deciding in advance which patients are likely to gain the most benefit from chemotherapy and which patients are less likely to benefit from chemotherapy. The aim of this study is to assess the changes in DNA and proteins in the cancer that occur as a result of chemotherapy.

Who can participate?

Patients aged 18 and over with cancer of the gullet

What does the study involve?

All patients receive two cycles of chemotherapy given 3 weeks apart. Tissue is taken from the cancer before and 4-6 weeks after the last dose of chemotherapy to assess DNA repair gene activity. The patients' clinical outcomes (disease-free and overall survival) are assessed at 6-12 months after chemotherapy.

What are the possible benefits and risks of participating?

This study will allow researchers to understand better which types of tumour respond best to this type of chemotherapy and how the tumour changed during treatment.

Where is the study run from?

Oxford University Hospital NHS Trust (UK)

When is the study starting and how long is it expected to run for?

January 2006 to November 2010

Who is funding the study?

1. Wellcome Trust (UK)

2. NIHR Biomedical Research Centre Oxford (UK)
3. Oxford University Clinical Academic Graduate School (UK)
4. NIHR University College Hospitals Biomedical Research Centre (UK)
5. Cancer Research UK Experimental Cancer Medicine Centre (UK)

Who is the main contact?

Dr Mark Middleton

Contact information

Type(s)

Scientific

Contact name

Dr Mark Middleton

Contact details

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Additional identifiers

EudraCT/CTIS number

2005-000834-34

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Version 2.1 20.10.05

Study information

Scientific Title

Phase II trial of neo-adjuvant Oxaliplatin and 5-fluorouracil in esophageal cancer

Study objectives

DNA damage repair gene expression in tumours can predict clinical outcomes following chemotherapy and surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Study design

Non-randomized phase 2 clinical trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Esophageal cancer

Interventions

All patients received Oxaliplatin 130 mg/m² IV on day 1, followed by 5FU 1gm/m² per day on days 1-4. Two cycles given 3 weeks apart. Follow-up was for 6 months after the last cycle of chemotherapy.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Oxaliplatin, 5-fluorouracil

Primary outcome measure

1. DNA repair gene expression in tumour tissue, measured using microarray at baseline and 4-6 weeks after the last dose of chemotherapy.
2. Clinical outcomes, measured using disease-free survival and overall survival at 6-12 months post chemotherapy

Secondary outcome measures

Haplotype and DNA repair gene pathways measured using immunohistochemistry at baseline and 4-6 weeks after the last dose of chemotherapy

Overall study start date

20/01/2006

Completion date

30/11/2010

Eligibility

Key inclusion criteria

1. Histologically proven operable oesophageal adenocarcinoma/squamous cell carcinoma
2. Age greater than or equal to 18 years
3. Suitable for neo-adjuvant chemotherapy according to local protocols
4. Subjects must be free of any clinically significant disease other than oesophageal cancer that would interfere with the study evaluations
5. Adequate haematologic, renal and hepatic function as demonstrated by laboratory values performed within 14 days prior to the administration of chemotherapy:
 - 5.1. Absolute neutrophil count (ANC) $\geq 1500/\text{mm}^3$
 - 5.2. Platelet count $\geq 100,000/\text{mm}^3$
 - 5.3. Haemoglobin $\geq 10\text{g/dL}$
 - 5.4. Urea and serum creatinine < 1.5 times upper limit of laboratory normal (ULN)
 - 5.5. Creatinine clearance: more than 50ml (by Cockcroft Gault calc)
 - 5.6. Total bilirubin < 1.5 times ULN
 - 5.7. AST ≤ 3 times ULN
 - 5.8. Alkaline phosphatase < 2 times ULN
6. Patients must have given written informed consent
7. Women of child-bearing potential must use an acceptable method of birth control during the study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

38

Key exclusion criteria

1. Women who are pregnant or nursing (pregnancy test to be performed within 24 hours prior to starting the study drug(s))
2. Known dihydropyrimidine dehydrogenase deficiency
3. Subjects known to be HIV, Hep B or Hep C positive

Date of first enrolment

01/05/2006

Date of final enrolment

01/02/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Oxford University Hospital NHS Trust

United Kingdom

OX3 7LE

Sponsor information

Organisation

Churchill Hospital

Sponsor details

Department of Oncology

Old Road

Headington

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England

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/009vheq40>

Funder(s)

Funder type

Research organisation

Funder Name

Wellcome Trust

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

Funder Name

NIHR Biomedical Research Centre Oxford

Funder Name

Oxford University Clinical Academic Graduate School

Funder Name

NIHR University College Hospitals Biomedical Research Centre

Funder Name

Cancer Research UK Experimental Cancer Medicine Centre

Results and Publications

Publication and dissemination plan

Full paper to be published in a scientific journal within the next 6 months.

Intention to publish date

01/01/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study have been archived and are no longer available.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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Results article	results	05/04/2016	Yes	No
Results article	results	08/05/2018	Yes	No