ISRCTN18146225 https://doi.org/10.1186/ISRCTN18146225

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

Registration date
12/10/2017

Overall study status
Completed

Last Edited
07/08/2018

Condition category
Cancer

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

Clinical Trials Information System (CTIS)
2005-000834-34

Protocol serial number
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)
Oxfordshire Regional Ethics Committee, 05/03/2006

Study design

Non-randomized phase 2 clinical trial

Primary study design
Interventional

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
Haplotype and DNA repair gene pathways measured using immunohistochemistry at baseline and 4-6 weeks after the last dose of chemotherapy

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) ≥ 1500/mm3
5.2. Platelet count ≥ 100,000/ mm3

5.3. Haemoglobin ≥ 10g/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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
Oxford University Hospital NHS Trust
United Kingdom
OX3 7LE

Sponsor information

Organisation
Churchill Hospital

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

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?
Results article	results	05/04/2016		Yes	No
Results article	results	08/05/2018		Yes	No