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Pre-operative chemotherapy for cancer of the oesophagus

Submission date 28/02/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/02/2001	**Overall study status** Completed	
Last Edited 22/02/2010	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
OE02

Study information

Scientific Title

Study objectives
To investigate in patients considered to have resectable cancer of the oesophagus whether pre-operative chemotherapy:

1. Prolongs survival
2. Affects physical well-being

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cancer

Interventions
1. One group receives pre-operative chemotherapy followed by surgery
2. The other group = Control group receives surgery alone

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Survival time

Key secondary outcome(s)
Not provided at time of registration

Completion date
30/06/1998

Eligibility

Key inclusion criteria
1. Tumour considered resectable
2. No evidence of cervical lymph node involvement or metastases
3. Creatinine clearance ≥60 ml/min
4. Total white blood cell count ≥3.5 x 109l
5. Platelet count ≥100 x 109l

6. No indication for urgent resection
7. No previous chemotherapy, radiotherapy or surgery for current oesophageal cancer
8. No other previous or concomitant malignant disease

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/02/1992

Date of final enrolment
30/06/1998

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
Results article	long term results	20/10/2009		Yes	No