ISRCTN43987580 https://doi.org/10.1186/ISRCTN43987580

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

Contact name
Dr James Lyddiard

Contact details
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Survival time

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/1992

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
800

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
England

United Kingdom

Study participating centre

MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	long term results	20/10/2009		Yes	No