Co-operative surgical trial for gastric cancer

Submission date 28/02/2001	Recruitment status No longer recruiting	
Registration date 28/02/2001	Overall study status Completed	[[X
Last Edited 21/01/2019	Condition category Cancer	[_]

] Prospectively registered

-] Protocol
-] Statistical analysis plan
- X] Results
-] Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers ST01

Study information

Scientific Title

Co-operative surgical trial for gastric cancer

Study objectives

To compare the effectiveness of more radical (R2) resection to the R1 resection with respect to the endpoints.

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) Not Specified

Participant information sheet

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

Interventions

Arm 1: conventional (R1) resection of tumour. Arm 2: radical (R2) resection of tumour.

Intervention Type Other

Phase Not Specified

Primary outcome measure

- 1. Operative morbidity and mortality (within 6 weeks of surgery)
- 2. Post-operative sequelae
- 3. Survival with and without evidence of cancer
- 4. Local recurrence
- 5. Site and distribution of metastatic disease

Secondary outcome measures

Not provided at time of registration

Overall study start date 01/01/1986

Completion date 01/11/1993

Eligibility

Key inclusion criteria Histologically or cytologically proven invasive gastric adenocarcinoma (stage I-III).

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants 400

Key exclusion criteria The patient must not have a perforated gastric carcinoma requiring emergency surgery.

Date of first enrolment 01/01/1986

Date of final enrolment 01/11/1993

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?
<u>Results article</u>	preliminary results	13/04/1996		Yes	No
<u>Results article</u>	5-year survival results	01/03/1999		Yes	No