MRC Adjuvant Gastric Infusional Chemotherapy Trial

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|------------------------------|---|--|--|--|
| 06/04/2000 | | ☐ Protocol | | |
| Registration date 06/04/2000 | Overall study status Completed | Statistical analysis plan | | |
| | | [X] Results | | |
| Last Edited | Condition category | [] Individual participant data | | |
| 28/10/2021 | Cancer | | | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Ms Monica Verma

Contact details

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not@provided.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ST02

Study information

Scientific Title

MRC Adjuvant Gastric Infusional Chemotherapy Trial

Acronym

MAGIC

Study objectives

To investigate whether peri-operative chemotherapy prolongs survival

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Two armed, randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Gastrointestinal cancer

Interventions

Three cycles of pre- and post-operative ECF (Epirubicin, Cisplatin and 5-Fluorouracil) chemotherapy versus surgery alone.

Follow-up: all patients will be followed 6 monthly to 2 years then annually until death.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Chemotherapy

Primary outcome measure

- 1. Survival time
- 2. Disease-free survival
- 3. Quality of life
- 4. Tumour response

Secondary outcome measures

Not provided at time of registration

Overall study start date

20/06/1994

Completion date

31/12/2001

Eligibility

Key inclusion criteria

- 1. Histologically proven adenocarcinoma (Stage II or greater) of the lower third oesophagus or stomach, that is considered to be non-urgently resectable with no evidence of distant metastasis
- 2. Suitable and fit for cytotoxic chemotherapy
- 3. WHO performance status of 0 or 1

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

500

Key exclusion criteria

- 1. Other malignant disease other than non-melanomatous skin cancer or in situ carcinoma of the cervix;
- 2. previous cytotoxic chemotherapy or radiotherapy

Date of first enrolment

20/06/1994

Date of final enrolment

31/12/2001

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 (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

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details Results | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------------|---------------------------|--------------|------------|----------------|-----------------|
| Results article | | 06/07/2006 | | Yes | No |
| Plain English results | | | 28/10/2021 | No | Yes |