

Adjuvant treatment of gastric cancer with preoperative intraperitoneal mitomycin-C bound to carbon particles

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/10/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MMC-CH

Study information

Scientific Title

Adjuvant treatment of gastric cancer with preoperative intraperitoneal mitomycin-C bound to carbon particles

Study objectives

Not provided at time of registration

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

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Stomach cancer

Interventions

1. Group A: Standard surgical resection plus 400 mg cimetidine daily for 12 months
2. Group B: Standard surgical resection with the intraperitoneal introduction of 50 mg Mitomycin-C bound to carbon particles just prior to surgical closure plus 400 mg cimetidine daily for 12 months

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Mitomycin-C, cimetidine

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1990

Completion date

31/12/1995

Eligibility

Key inclusion criteria

1. Histologically documented adenocarcinoma of the stomach
2. All patients should have undergone surgery for resection of their primary malignancy
3. No evidence of distant or metastatic disease other than removable N1 or N2 lymph node metastases
4. No prior chemotherapy, radiotherapy or immunotherapy
5. Age <75 years and life expectancy greater than 3 months
6. Ambulatory performance status Karnofsky Grading 80%
7. Adequate bone marrow function
8. No evidence of organ failure
9. No evidence of intercurrent disease from previous malignancy

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1990

Date of final enrolment

31/12/1995

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Leicester General Hospital (UK)

Sponsor details

Gwendolen Road

Leicester

England

United Kingdom

LE5 4PW

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/02zg49d29>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leicester General Hospital (UK)

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