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

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 24/10/2019	**Condition category** Cancer	

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