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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
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Contact details
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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

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
United Kingdom

England

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Leicester General Hospital (UK)

ROR
https://ror.org/02zg49d29

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leicester General Hospital (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration