

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

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 24/10/2019	<b>Condition category</b> 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

### 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

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**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