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A Randomised, Double Blind, Placebo Controlled Study to Assess the Effects of Ranitidine on the Survival of Patients with Gastric Cancer

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 13/11/2012	**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
RANM09

Study information

Scientific Title

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)

Health condition(s) or problem(s) studied
Gastric Cancer

Interventions
1. Arm A: Ranitidine 50 mg in 20 ml 0.9% saline or 5% dextrose to be given intravenously three times daily until oral treatment is tolerated. This will be followed by ranitidine 150 mg tablet twice daily until death or for a period of 5 years.

2. Arm B: Placebo 50 mg in 20 ml 0.9% saline or 5% dextrose to be given intravenously three times daily until oral treatment is tolerated. This will be followed by placebo 150 mg tablet twice daily until death or for a period of 5 years.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ranitidine

Primary outcome(s)
Not provided at time of registration

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

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Aged <18 years
2. Gastric cancer proven by histology and endoscopy or barium meal
3. Patients selected for laparotomy must commence intravenous treatment with study drug at the time of induction of anaesthesia
4. Adequate renal function
5. No previous resection for gastric cancer
6. No other prior or concurrent malignancy
7. No treatment with systemic steroids, hormones or other know immunomodulating drugs within the last 7 days prior to the start of the study period
8. No medical contraindications to study treatments

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2001

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Glaxo Wellcome (UK)

ROR
https://ror.org/01xsqw823

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline (UK)

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary