

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	<input type="checkbox"/> Prospectively registered
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/11/2012	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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
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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

Study design

Randomised controlled trial

Primary study design

Interventional

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 known 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