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A Randomised Double-Blind Multicentre Placebo-Controlled Study to Investigate the Effect of Ranitidine on the Post-Operative Infection Rate and Survival Rate of Patients Undergoing Surgery for Colorectal Cancer

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 11/07/2014	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
RANX05

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
Colon, Rectum

Interventions
1. Group A: Intravenous ranitidine, 100 mg, administered twice daily for 5 days or until oral treatment is tolerated, followed by oral ranitidine, 150 mg twice daily until death or for a period of 5 years.
2. Group B: Intravenous placebo, 100 mg, administered twice daily for 5 days or until oral treatment is tolerated, followed by oral placebo, 150 mg 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
31/12/2002

Eligibility

Key inclusion criteria
1. Aged >18 years
2. Diagnosis of colorectal cancer
3. This is the first operation for cancer and the life expectancy of the patient is at least 3 months at the time of surgery
4. No concurrent chronic modulating therapy with systemic steroids, antiviral agents or other known immunomodulating drugs
5. No systemic antimicrobial agents in the 48 h prior to entry into the study
6. Not currently or planning to undergo chemotherapy, radiotherapy or any other therapy for cancer
7. No medical contraindications to protocol 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
01/01/2002

Date of final enrolment
31/12/2002

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