ISRCTN14545665 https://doi.org/10.1186/ISRCTN14545665

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	Recruitment status	[ ] Prospectively registered
19/08/2002	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/08/2002	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/07/2014	Cancer	[ ] 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
UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2002

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

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

Sponsor information

Organisation
Glaxo Wellcome (UK)

Sponsor details
Stockley Park West
Uxbridge, Middlesex
United Kingdom
UB11 1BT

Sponsor type
Industry

Website
http://uk.gsk.com

ROR
https://ror.org/01xsqw823

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline (UK)

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

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration