

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/07/2014	Condition category 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

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