

Quality Initiative in Rectal Cancer trial

Submission date 18/11/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 15/08/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/11/2013	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Marko Simunovic

Contact details

Juravinski Cancer Centre
699 Concession Street
Hamilton, ON
Canada
L8V 5C2
+1 905 575 6365
marko.simunovic@hrcc.on.ca

Additional identifiers

ClinicalTrials.gov (NCT)

NCT00182130

Protocol serial number

MCT-50013

Study information

Scientific Title

Acronym

QIRC

Study objectives

To test if the quality initiative in rectal cancer strategy, which is designed to positively influence surgeon practice, can decrease hospital rates of permanent colostomy and local tumour recurrence for surgically treated rectal cancer patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the McMaster University Research Ethics Board on the 30th August 2001.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Rectal cancer

Interventions

Surgeons in the 8 hospitals allocated to the experimental arm will be exposed to the QIRC strategy. The strategy includes a workshop, operative demonstrations, use of opinion leaders, audit and feedback, and a post-operative questionnaire. Hospitals in the control arm represent the normal practice environment.

Accrual closed effective on the 11th December, 2004 (we are now conducting patient follow up as per protocol; minimum 30 month follow up; study follow up will be completed June 30, 2007).

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Rate of permanent colostomy
2. Rate of local recurrence

Key secondary outcome(s)

1. Bowel, bladder and sexual function
2. Quality of life

Completion date

31/05/2006

Eligibility

Key inclusion criteria

Hospital criteria:

An Ontario hospital with a procedure volume of 15 or more major rectal cancer resections per year for fiscal years 1996 to 1998.

Patient criteria:

1. Persons of either sex, age groups 18 and above
2. Consecutive patients undergoing major rectal cancer surgery
3. Tumor located within 15 cm of anal verge by rigid sigmoidoscopy, or, at or below the level of the sacral promontory at the time of surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Does not comply with the above criteria.

Date of first enrolment

01/05/2002

Date of final enrolment

31/05/2006

Locations

Countries of recruitment

Canada

Study participating centre

Juravinski Cancer Centre
Hamilton, ON
Canada
L8V 5C2

Sponsor information

Organisation

Juravinski Cancer Centre (Canada)

ROR

<https://ror.org/02cwjh447>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-50013)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2013		Yes	No
Results article	results	01/12/2013		Yes	No
Protocol article	protocol	15/02/2008		Yes	No