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Quality Initiative in Rectal Cancer trial

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00182130

Secondary identifying numbers
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.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
01/05/2002

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
672 (total patients accrued = 1015)

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)

Sponsor details
699 Concession Street
Hamilton, Ontario
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Sponsor type
Government

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

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

Study outputs

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