# Quality Initiative in Rectal Cancer trial

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

## 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.

#### Study design

Randomised controlled trial

### Primary study design

Interventional

#### 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

## **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