

# The effective management of radiation-induced bowel injury: a randomised controlled trial

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/03/2022	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-study-to-improve-treatment-for-side-effects-of-radiotherapy-to-the-bowel>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

N0258191022

## Study information

### Scientific Title

The effective management of radiation-induced bowel injury: a randomised controlled trial

**Study objectives**

To assess which tests can help decide the cause of these patients symptoms' whether treatments in fact improve patients' quality of life and whether these treatments can be delivered usefully by a specialist nurse.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The Royal Marsden Research Ethics Committee (now merged with South West London REC1), 26/03/2007, ref: 07/Q0801/47

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**Study type(s)**

Quality of life

**Health condition(s) or problem(s) studied**

Injury, Occupational Diseases, Poisoning: Radiation

**Interventions**

Randomised test intervention vs standardised intervention, non-blinded (Phase III).  
Observational (no treatment or diagnostic intervention), Quality of Life Assessment, Qualitative Study

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Improvement in gastrointestinal symptoms

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

31/07/2012

**Eligibility****Key inclusion criteria**

Patients who have a life expectancy of more than 1 year and who have received radical pelvic radiotherapy with curative intent six months previously and who subsequently have developed new onset troublesome gastrointestinal symptoms

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**Total final enrolment**

218

**Key exclusion criteria**

Added May 2008:

1. Patient refusing to give informed consent
2. Patients deemed by their clinical oncologist to require immediate gastroenterological assessment

**Date of first enrolment**

26/11/2007

**Date of final enrolment**

12/12/2011

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Royal Marsden NHS Trust

London

United Kingdom

SW3 6JJ

**Sponsor information****Organisation**

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

# Funder(s)

## Funder type

Government

## Funder Name

The Royal Marsden NHS Foundation Trust (UK)

# Results and Publications

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Plain English results</a>		23/07/2018	29/03/2022	No	Yes