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

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
28/09/2007		☐ Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
28/09/2007		<ul><li>Results</li><li>Individual participant data</li></ul>		
Last Edited				
29/03/2022	Injury, Occupational Diseases, Poisoning	☐ 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

Dr Jervoise Andreyev

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

### Study type(s)

Quality of life

## Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

## 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 measure

Improvement in gastrointestinal symptoms

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

01/07/2007

#### 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

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

#### Target number of participants

250 RMH participants

#### 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

#### England

**United Kingdom** 

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

#### Sponsor details

The Department of Health, Richmond House, 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

#### Sponsor type

Government

#### Website

http://www.dh.gov.uk/Home/fs/en

# Funder(s)

## Funder type

Government

#### **Funder Name**

The Royal Marsden NHS Foundation Trust (UK)

## **Results and Publications**

Publication and dissemination plan

## Not provided at time of registration

## Intention to publish date

## 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?
Plain English results		23/07/2018	29/03/2022	No	Yes