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

Submission date	Recruitment status	[X] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
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

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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
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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