

Using a narrative analysis, what is the lived experience of people (and their partners where appropriate) who have gastrointestinal symptoms following pelvic radiotherapy for pelvic cancer

Submission date 16/05/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/05/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/03/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

See <https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-understand-peoples-experiences-after-having-radiotherapy-to-the-pelvis>

Contact information

Type(s)

Public

Contact name

Mrs Helen Ludlow

Contact details

Department of Gastroenterology
University Hospital Llandough
Penarth
United Kingdom
CF64 2XX
029 20716403
helens@cardiff.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

201783

ClinicalTrials.gov number

Secondary identifying numbers

IRAS 201783

Study information

Scientific Title

Improving awareness among health care professionals of what people experience when they have bowel problems after pelvic radiotherapy via narrative analysis

Study objectives

The number of people surviving a cancer diagnosis is growing and yet so are the unintended consequences of the cancer treatment. When radiotherapy is given to treat pelvic cancers up to 90 % of patients may have late GI symptoms, now known as Pelvic Radiation Disease (PRD). Whereas there are quantitative studies measuring quality of life in this group of people there is very little qualitative data regarding lived experience- what is it like to have life-changing bowel problems after completing the cancer treatment. It is hoped that this study will raise awareness amongst health care professionals about PRD and improve the current availability of specialist gastroenterology treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Board is Health Care Research Wales, 09/06/2016, ref: 16/WA/0126

Study design

Single site observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format. Please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Pelvic Radiation Disease

Interventions

A narrative analysis will be used to analyse the qualitative interviews to gain an understanding of the experience of living with PRD. Each participant will have an interview lasting approximately 1 hour. This will be face-to face, either in the participant's home or the Out-Patient Department. The narrative analyses will depend on the patients response to the interview.

Intervention Type

Other

Primary outcome measure

Life stories in narrative form, created by collecting peoples experiences of living with PRD (via face-to-face interviews) and developing a narrative to improve health care professionals understanding

Secondary outcome measures

N/A

Overall study start date

01/10/2015

Completion date

01/06/2017

Eligibility

Key inclusion criteria

1. Aged >18 years
2. Been referred to the PRD clinic in the trial site hospital with bowel problems at least 6 months post-completion of pelvic radiotherapy

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Approximately 10 participants

Key exclusion criteria

Unable to participant in an interview

Date of first enrolment

01/08/2016

Date of final enrolment

01/03/2017

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

University Hospital Llandough

Penlan Road

Llandough

Penarth

The Vale of Glamorgan

United Kingdom

CF64 2XX

Sponsor information

Organisation

Cardiff University

Sponsor details

School of Healthcare Sciences

Eastgate House

Newport Road

Cardiff

Wales

United Kingdom

CF24 0AB

029 20687555

gamblingts@cardiff.ac.uk

Sponsor type

University/education

ROR

<https://ror.org/03kk7td41>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Publish in a high impact peer reviewed journal.

Intention to publish date

01/10/2019

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		03/09/2018	03/09/2018	No	No
Plain English results			05/03/2020	No	Yes
HRA research summary			28/06/2023	No	No