

The clinical benefit and cost effectiveness of a gastrointestinal care bundle for patients undergoing pelvic chemoradiotherapy

Submission date 10/07/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/07/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/11/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/trials/a-study-looking-care-package-people-having-chemoradiotherapy-cervical-cancer-bladder-cancer>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

12773

Study information

Scientific Title

The clinical benefit and cost effectiveness of a gastrointestinal care bundle for patients undergoing pelvic chemoradiotherapy: a randomised controlled pilot study

Study objectives

The specific aim of this pilot study is to test the process of recruitment, randomisation, investigation, treatment and follow up assessments and to provide provisional data on which to design and power a multicentre randomised controlled trial to determine if a gastrointestinal care bundle, including nutritional intervention and detecting and treating lactose intolerance, small bowel bacterial overgrowth and bile acid malabsorption, improves GI symptoms in the short-term.

Ethics approval required

Old ethics approval format

Ethics approval(s)

12/NW/0160

Study design

Non-randomised; Interventional and Observational; Design type: Not specified, Process of Care, Cohort study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

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

Topic: Cancer; Subtopic: Bladder Cancer, Gynaecological Cancer; Disease: Bladder (advanced), Bladder (superficial), Cervix

Interventions

Gastrointestinal Care Bundle, Nutritional intervention and detecting and treating lactose intolerance, small bowel bacterial overgrowth and bile acid malabsorption

Study Entry : Single Randomisation only

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Gastrointestinal symptoms as determined by CTCAE pelvic symptom questionnaire; Timepoint (s): Immediately post-treatment (week 6)

Secondary outcome measures

Not provided at time of registration

Overall study start date

06/12/2012

Completion date

01/10/2015

Eligibility**Key inclusion criteria**

1. Age ≥18 years
2. Histologically confirmed cervical or bladder cancer
3. Patients undergoing potentially curative chemoradiotherapy
4. Ability to give informed consent to participate

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment

50

Key exclusion criteria

1. Age <18 years
2. No histological diagnosis of cervical or bladder cancer

3. Patients unable to complete patient-reported questionnaires
4. Unable to give informed consent
5. Pre-existing GI disease

Date of first enrolment

06/12/2012

Date of final enrolment

01/10/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

550 Wilmslow Road

Manchester

United Kingdom

M20 4BX

Sponsor information

Organisation

Christie Hospital NHS Foundation Trust (UK)

Sponsor details

550 Wilmslow Road

Manchester

England

United Kingdom

M20 4BX

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/03v9efr22>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK)

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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	01/08/2020	04/11/2020	Yes	No