

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

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

### Protocol serial number

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

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**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**

United Kingdom

England

**Study participating centre**  
**550 Wilmslow Road**  
Manchester  
United Kingdom  
M20 4BX

## Sponsor information

### Organisation

Christie Hospital NHS Foundation Trust (UK)

### 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

**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?
<a href="#">Results article</a>	results	01/08/2020	04/11/2020	Yes	No