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

Submission date	Recruitment status	[_] Prospectively registered
10/07/2014	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
10/07/2014	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
04/11/2020	Cancer	

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 regsitration

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