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Dietary fibre supplementation to reduce side effects of prostate radiotherapy (DIETRICH study)

Submission date
01/12/2025

Recruitment status
Not yet recruiting

Registration date
06/01/2026

Overall study status
Ongoing

Last Edited
23/01/2026

Condition category
Cancer

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
One of the treatments for prostate cancer is radiotherapy. Whilst this can help to treat the cancer, it
can lead to bowel and bladder complications such as diarrhoea, discomfort, more frequent urination
and bleeding. Approximately 1 in 2 men can suffer from these side effects. Side-effects can remain
for some time once treatment is completed which leads to further complications and can affect quality of life.
There is evidence that a dietary fibre supplement may help with some radiotherapy side effects. In
the DIETRICH study, we want to investigate if men who have their diet supplemented with a dietary
fibre source called inulin before radiotherapy starts, during treatment and for a short time after, have
fewer gut-associated side effects than those who do not take extra fibre. Inulin is a natural substance from plants such as chicory root. It works by boosting the good bacteria in the gut which
helps to reduce inflammation in the lower gut and might lead to fewer side-effects.

Who can participate?
We aim to recruit 220 men who have opted for radiotherapy treatment for their prostate cancer.

What does the study involve?
Half the men who take part in DIETRICH will be given a supply of inulin to take for 2 weeks before
radiotherapy, 4 weeks during radiotherapy and for 3 weeks after. The other half will receive a treatment which will look and taste similar to inulin but will not include any fibre (placebo treatment).
Participants will not know what treatment they are given. Participation in the DIETRICH study

will be
for a total of 18 weeks. During this time participants will answer some questions on symptoms and
diet. Faecal (poo) samples will be collected before and after radiotherapy to study the bacteria and
substances in them. This will help us understand how inulin may reduce side-effects and improve gut health.

What are the possible benefits and risks of participating?
You may experience fewer gut-related side effects from radiotherapy, but this cannot be guaranteed. Taking part will help researchers learn more about how diet can improve gut health during cancer treatment. Risks are minimal, but some people may experience mild digestive changes from the fibre supplement.

Where is the study run from?
University of Aberdeen (UK)
NHS Grampian (UK)

When is the study starting and how long is it expected to run for?
January 2026 to February 2028

Who is funding the study?
Prostate Cancer UK

Who is the main contact?
dietrich@abdn.ac.uk

Contact information

Type(s)
Public

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Type(s)
Principal investigator, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
355096

Central Portfolio Management System (CPMS)
72064

Study information

Scientific Title
Phase 2 randomised controlled trial of effects of the dietary fibre supplement inulin versus placebo on intestinal and urinary side effects in men receiving standard of care radiotherapy for intermediate/high risk localised or locally advanced prostate cancer

Acronym
DIETRICH

Study objectives
Primary Objective
The primary objective is to evaluate if supplemental inulin starting two weeks prior to and during radiotherapy is advantageous over treatment as usual (which may include rescue psyllium husk or other medication as part of standard of care when bowel symptoms develop during treatment). The primary outcome will be measured by the bowel domain of EPIC-26 at 4-weeks after starting radiotherapy.

Secondary Objectives
(a) Does inulin supplementation:
1. Reduce acute urinary toxicity, as assessed by both EPIC-26 urinary domains?
2. Reduce bowel and bladder toxicity in clinician-reported assessments, measured using the Common Terminology Criteria for Adverse Events (CTCAE)?
3. Improve overall quality of life and reduce treatment related symptoms (measured by EORTC QLQ-C30)
b) To evaluate changes in the bacterial composition and resulting metabolites, including short-chain fatty acids (SCFAs), in faecal samples of men before and after inulin/placebo supplementation and radiotherapy, using 16S rRNA gene sequencing and gas chromatography, respectively. This data will be compared with intestinal and urinary toxicity, as well as food and nutrient intake.
c) To assess the effect of inulin/placebo supplementation on intestinal inflammatory responses (via calprotectin levels in faeces) to radiotherapy.

d) To assess the feasibility of identifying surrogate biomarkers that distinguish responders from non-responders to inulin in terms of reduction in acute radiotherapy toxicity. This will involve 16S sequencing and other translational biomarkers (e.g., calprotectin, SCFAs) and will contribute to the development of biomarkers for a future Phase 3 clinical trial.
e) To determine participants' habitual diet at baseline and Week 16. This will include the assessment of baseline fibre intake and diet quality, as well as the pro- or anti-inflammatory nature of the habitual diet. Additionally, the study will explore any dietary changes or improvements resulting from participants' involvement in the study.

Tertiary Objectives
To assess hormonal and sexual function in response to inulin/placebo supplementation (measured by the hormonal and sexual domains of the EPIC-26).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/12/2025, London - Central Research Ethics Committee (3rd Floor, 3 Piccadilly Place, London Road, HRA Manchester Centre, Manchester, M1 3BN, United Kingdom; +44 207 1048285; londoncentral.rec@hra.nhs.uk), ref: 25/LO/0887

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Health services research, Prevention, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Prevention of acute bowel toxicity and urinary side effects in men undergoing radiotherapy for prostate cancer.

Interventions
We will aim to recruit 220 men who have opted for radiotherapy treatment for their prostate cancer. Half the men who take part in DIETRICH will be given a supply of inulin to take for 2 weeks before radiotherapy, 4 weeks during radiotherapy and for 3 weeks after. The other half will receive a treatment (maltodextrin) which will look and taste similar to inulin but will not include any fibre (placebo treatment). Participants will be asked to take 16g daily of the inulin

/maltodextrin (placebo); 8g in the morning and 8g in the evening. The inulin/maltodextrin (placebo) which will be in powdered form and can be added to cold drinks and taken orally. Participants will not know what treatment they are given. Participation in the DIETRICH study will be for a total of 18 weeks. During this time participants will answer some questions on symptoms and diet. Faecal samples will be collected before and after radiotherapy to study the bacteria and substances in them. This will help us understand how inulin may reduce side-effects and improve gut health. Randomisation will occur once all eligibility criteria are confirmed and informed consent obtained. A computerised randomisation system created by CHaRT will be used to randomise participants in a 1:1 ratio to inulin or maltodextrin (placebo), stratified by centre and nodal treatment (yes/no).

Intervention Type
Supplement

Primary outcome(s)
1. Bladder toxicity measured using EPIC-26 (Expanded Prostate Cancer Index Composite short form) at Week 4

Key secondary outcome(s))
1. Bowel and bladder toxicity measured using EPIC-26 at week –2, week 0, week 6, week 10 and week 16

2. General quality of life measured using EORTC-QLQ-30 at week –2, week 0, week 4, week 6, week 10 and week 16

3. Bowel and bladder toxicity measured using CTCAE criteria at week –2, week 0, week 4 and week 6

4. Gut Microbiota and Dietary Impact on Acute Toxicities measured using 16S rRNA gene sequencing of faeces and dietary intake (through food frequency questionnaires (FFQ) and 3-day food diaries) at week –2, week 0, week 4

Tertiary outcome measures
Hormonal and sexual function measured by EPIC-26 at week –2, week 0, week 4, week 6, week 10 and week 16.

Completion date
29/02/2028

Eligibility

Key inclusion criteria
1. Men with intermediate/high risk localised or locally advanced prostate cancer planned to receive radical radiotherapy to the prostate with or without pelvic nodes.
2. Have Cambridge Prognostic Group (CPG) 3, 4 or 5 prostate cancer
3. T1-3 N0 M0
4. Receiving radical radiotherapy to the prostate with or without pelvic nodes (60 Gy in 20 fractions over 4 weeks)
5. Age ≥18 years
6. Are able and willing to give informed consent to participate and to participate in study procedures

7. Have a WHO performance status 0-2 (well enough to perform daily activities with only mild restrictions identified at screening/first visit).

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
Male

Total final enrolment
0

Key exclusion criteria
1. T4 disease
2. History of colectomy, stoma (ileostomy or colostomy), or other major gastrointestinal surgeries altering bowel anatomy
3. Prior radiotherapy to the prostate or pelvis
4. Prior radical prostatectomy
5. Prior androgen deprivation therapy (ADT) for >12 months at randomisation
6. Patient to have rectal spacer inserted for radiotherapy
7. Poorly controlled diabetes mellitus (Patient reported)
8. Coeliac disease
9. Known allergy to maltodextrin (placebo)
10. Known allergy to inulin
11. Life expectancy <5 years
12. Men without capacity

Date of first enrolment
01/04/2026

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Aberdeen Royal Infirmary
Department of Oncology, ANCHOR Unit, Clinic D, Foresterhill
Aberdeen
Scotland
AB25 2ZN

Study participating centre
Edinburgh Cancer Centre
Western General Hospital, Crewe Road South
Edinburgh
Scotland
EH4 2XU

Study participating centre
Beatson West of Scotland Cancer Centre
Department of Clinical Oncology, 1053 Great Western Rd
Glasgow
Scotland
G12 0YN

Study participating centre
St James's Teaching Hospital
Dept. of Radiotherapy, Radiotherapy research team, Floor 1, Bexley Wing, Beckett Street
Leeds
England
LS9 7TF

Study participating centre
The Clatterbridge Cancer Centre NHS Foundation Trust
Clatterbridge Hospital
Clatterbridge Road
Bebington
Wirral
England
CH63 4JY

Study participating centre

The Christie
550 Wilmslow Road
Withington
Manchester
England
M20 4BX

Study participating centre
Mount Vernon Cancer Centre
Rickmansworth Road
Northwood
England
HA6 2RN

Study participating centre
Rosemere Cancer Centre
Royal Preston Hospital, Sharoe Green Lane, Fullwood
Preston
England
PR2 9HT

Sponsor information

Organisation
University of Aberdeen

ROR
https://ror.org/016476m91

Organisation
NHS Grampian

ROR
https://ror.org/00ma0mg56

Funder(s)

Funder type

Funder Name
Prostate Cancer UK

Alternative Name(s)
Prostate Cancer, Prostate Action, ProstateUK, prostatecanceruk

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available