

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

Submission date 01/12/2025	Recruitment status Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/01/2026	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/04/2026	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

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Type(s)

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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 \geq 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

01/06/2026

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