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Indolent prostate cancer, phytochemicals and probiotics

Submission date
13/06/2023

Recruitment status
No longer recruiting

Registration date
19/06/2023

Overall study status
Completed

Last Edited
04/08/2025

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Emerging studies are linking poor gut health (dysbiosis) with greater risk and progression of prostate cancer (PCa). Various dietary and lifestyle factors influence dysbiosis but probiotic supplements have also been shown to improve the microbiome floral to a more favourable, less inflammatory profile. Likewise, studies have linked a higher intake of phytochemical-rich foods with a lower risk of PCa and progression of prostatic specific antigen (PSA), a protein produced by the prostate gland commonly used as a biomarker for prostate cancer detection and monitoring. Phytochemicals have numerous direct and indirect anti-cancer properties, including reducing excess chronic inflammation and enhancing oxidative pathways, but they also act as prebiotics, which supports commensal and ingested probiotic bacteria. The hypothesis for this study is that a probiotic supplement could enhance the benefits of a phytochemical-rich supplement via this synergistic effect. A combination of phytochemical-rich food and probiotic supplements has not previously been explored in a cohort of men with PCa, hence the rationale for this study. The aim of this study is to establish whether boosting the diet with a lactobacillus probiotic blend in addition to a phytochemical-rich food supplement will influence PSA progression. Secondary endpoints include an assessment of prostate-related symptoms (waterworks and erectile function) and well-being measured by grip strength.

Who can participate?
Adult men aged over 18 years old with histologically proven, early PCa, not taking androgen deprivation therapy (ADT), managed with surveillance

What does the study involve?
Following written informed consent, all men will be given the phytochemical-rich food supplement and asked to stop all other over-the-counter supplements. They will then be randomly assigned to take either a probiotic supplement or a placebo. The supplements will be taken twice a day for 4 months. The PSA doubling time (PSAdt), a method used to evaluate the progression and severity of prostate cancer based on changes in PSA levels over time, will be taken at baseline and 4 months together with measures of prostate symptoms and wellbeing.

The probiotic capsule will contain 10 billion colony-forming units (CFU) of 5 lactobacillus strains with built-in prebiotics. The phytochemical-rich capsule will contain whole foods which have

previously reported potential benefits for men with PCa in epidemiological, laboratory and prospective studies (broccoli, green tea, pomegranate, turmeric, cranberry and ginger). The ingredients of both supplements have been shown to have a high safety profile in previous studies.

What are the possible benefits and risks of participating?
The possible benefits include the financial side, as men can stop all over-the-counter supplements, which many men already take - many will save money. Most men have a strong interest in nutrition and self-empowerment strategies so hopefully this study should provide welcomed information.

The possible risks include that both these food supplements have been used in previous studies with a low incidence of side effects with no significant reported adverse event. Mild abdominal Bloating occurred in 3% of participants - this is a possible side effect is this study.

Where is the study run from?
Bedford Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2023 to October 2024

Who is funding the study?
Bedford Hospital Research Fund (UK)

Who is the main contact?
Prof Robert Thomas, robert.thomas@bedfordhospital.nhs.uk (UK)

Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
321309

Study information

Scientific Title
Do probiotics aid men with indolent prostate cancer in addition to phytochemical-rich whole foods? A randomised, double-blind, placebo-controlled trial

Acronym
The YourPhyto Study

Study objectives
A food capsule, containing lactobacillus probiotic, in addition to a phytochemical-rich whole food capsule, could have an influence on prostate-specific antigen (PSA) progression compared to men taking a phytochemical-rich whole food supplement alone, among men with prostate cancer, managed with surveillance.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/10/2023, East Midlands - Nottingham 1 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8115; Nottingham1.rec@hra.nhs.uk), ref: 321309

Study design
Randomized double-blind controlled study

Primary study design
Interventional

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Indolent prostate cancer

Interventions
This is a double-blind, randomised, controlled trial in men who have a diagnosis of indolent prostate cancer managed with surveillance alone. Following written informed consent, patients will be randomised (1:1) to:
• Men in one randomised arm (blinded) will receive a phytochemical-rich food supplement (PFS) containing whole dried pomegranate, turmeric, green tea, broccoli, cranberry and ginger plus a probiotic capsule containing a blend of 10 billion colony-forming units (CFU) of 5 lactobacilli plus inulin and low dose cholecalciferol as prebiotics.
• Men in the other blinded randomised group will be given the PFS plus placebo
Each capsule will be taken twice a day, for 4 months. Participants are asked to stop all other over-the-counter supplements
The phytochemical-rich capsule contains dried whole foods which have previously been reported as safe among men with prostate cancer in prospective studies. The ingredients of both supplements have been shown to have a high safety profile. This blend has been used in two previous studies and was safe and well-tolerated.

Computer generated Block Randomisation will be employed. A spreadsheet will be created; in column 1, sequential participant numbers will be recorded. In column 2, block-generated randomised Arms (A or B), will be recorded. After a participant has consented they will be allocated the next trial number and randomised Arm in strict order. Participants will be given a four-month supply of either "A" or "B" plus the whole food supplement.

Contact will be face-to-face consultations with the medical team at baseline and at trial termination during their routine clinical management for surveillance. Location: Primrose Oncology Research Unit within the Oncology department of Bedford Hospital, Bedfordshire Hospitals NHS Foundation Trust, which specialises in Prostate cancer.

Prostatic specific antigen doubling time (PSAdt) will be taken at baseline and 4 months together with measures of prostate symptoms, erectile function and strength.

Intervention Type

Supplement

Primary outcome(s)
Prostatic specific antigen doubling time (PSAdt) measured using a routine blood test analysis at trial entry baseline and 4 months

Key secondary outcome(s))
The following secondary outcome measures will be assessed at baseline and 4 months:
1. Urinary symptoms measured using the International Prostate Symptoms score
2. Erectile function measured using the validated International Index of Erectile Function
3. Grip strength measured using a portable Hand help grip strength dynameter

Completion date
01/10/2024

Eligibility

Key inclusion criteria
1. Histologically confirmed prostate cancer
2. Written informed consent
3. No current androgen deprivation or other medication for prostate cancer
4. Patients who are willing to comply with an oral food supplement
5. Patients who are willing to cease all non-trial, over-the-counter oral food supplements
6. Patients considered for surveillance or watch and wait for strategy, following multidisciplinary team discussion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
Male

Total final enrolment
212

Key exclusion criteria
1. No histological diagnosis of prostate cancer
2. Not willing to stop other over-the-counter supplements

3. Patients with liver function tests more than twice the abnormal laboratory range
4. Patients with gastric or small bowel malabsorption or dysfunction
5. Patients with a known allergy to any of the trial food components.

Date of first enrolment
01/08/2023

Date of final enrolment
16/05/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bedford Hospital
Kempston Road
Bedford
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Sponsor information

Organisation
Bedford Hospital NHS Trust

ROR
https://ror.org/031nbgr73

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Bedford Hospital Research Fund

Results and Publications

Individual participant data (IPD) sharing plan

No personal patient identifying information will be available on any date. After the datasets for both randomised groups have been externally audited and statistically validated it will made available to the public, in an excel spread sheet on the trials website (A page on http://www.cancernet.co.uk)

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		18/02/2025	04/08/2025	No	No
Participant information sheet		24/05/2023	19/06/2023	No	Yes
Protocol file		17/05/2023	19/06/2023	No	No