

Prostate and Diet Study (ProDiet Study): dietary interventions for men at high risk of prostate cancer - feasibility study

| | | |
|--|---|---|
| Submission date 27/02/2009 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 13/03/2009 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 11/07/2019 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/trials-search/a-study-men-at-risk-prostate-cancer-can-increase-levels-lycopene-and-green-tea-prodiet>

Contact information

Type(s)

Scientific

Contact name

Dr Athene Lane

Contact details

Department of Social Medicine
Bristol University
Canyng Hall
39 Whatley Road
Bristol
United Kingdom
BS8 2PS

Additional identifiers

ClinicalTrials.gov (NCT)

NCT01105338

Protocol serial number

Protocol version 1.1 (07/07/2008)

Study information

Scientific Title

The feasibility of a randomised controlled trial of dietary interventions for men at high risk of prostate cancer: the ProDiet study

Acronym

ProDiet

Study objectives

This study aims to investigate the feasibility of recruiting men identified with an increased risk of prostate cancer into a randomised trial of dietary modification. Secondly, to investigate whether dietary modification results in elevated serum levels of the biological active dietary agents.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Trent Multi-centre Research Ethics Committee (MREC), approved on 16/12/2008 (ref: 08/H0405/61)

Study design

Randomised 3 x 3 factorial design double-blind feasibility trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

Participants will each be randomly allocated to one of three lycopene-based/matched placebo interventions, and one of three green-tea-based/placebo interventions. Men will be asked to follow their allocated interventions for six months.

Lycopene-based interventions:

1. Dietary advice regarding a daily portion of cooked tomatoes (rich in Lycopene) plus matched placebo tablets
2. Tomato-derived lycopene supplement capsules (oral) daily (30 mg) with control dietary advice recommending five daily portions of fruit and vegetables
3. Control dietary advice recommending five daily portions of fruit and vegetables plus matched placebo tablets

Green-tea-based interventions:

- A. Green tea capsules (oral) at 800 mg daily
- B. Matched placebo supplement capsules
- C. Advice to increase consumption of green tea

Intervention Type

Supplement

Primary outcome(s)

Serum lycopene and epigallocatechin-3-gallate (green tea) levels at six months following randomisation

Key secondary outcome(s)

1. Trial recruitment and randomisation rates (measured at each stage of the study flowchart)
2. Intervention tolerability (adverse event reporting during the six months of follow-up)
3. Compliance (returned tablet counts and self reported counts at six months)
4. Trial retention (participants completing the six month follow-up and the questionnaires)
5. PSA values (measured at one and six months)
6. Dietary compliance with recommendations (dietary questionnaire completed at six months and participant data reporting dietary change)
7. Weight and body mass index (measured at one and six months) to assess whether the interventions have beneficial or deleterious effects on weight
8. Blood pressure (measured at one and six months) to assess whether there are any overall health benefits to the healthy diets
9. Attitudes and views of men and their spouses about dietary modification and participation in long term trials. Only a subset of participants will be included in this part of the study (one qualitative interview per participant; conducted throughout the study).
10. Anxiety, depression and psychological state - measured by the Hospital Anxiety and Depression Scale and the Profile of Moods States at enrolment, one month and six months
11. Urinary symptoms - measured at enrolment, one month and six months by the International Continence Society 'male short-form' (ICSmaleSF) questionnaire, which includes voiding and incontinence scores, nocturia, frequency and urinary-specific quality of life care data sources

Completion date

30/09/2010

Eligibility

Key inclusion criteria

1. Age 50-69 years on the date of preparation of the list at the general practice of potential participants for the ProtecT study (registered with ISRCTN20141297)
2. Male gender
3. ProtecT participants with a prostate-specific antigen (PSA) test between 2.5 to 2.95 ng/ml or a PSA level of at least 3.0 ng/ml with a negative biopsy (10 core procedure) from the ProtecT study
4. Enrolled in the ProMPT study and willing to be contacted about further studies
5. Able to give informed written consent to participate
6. Registration with the participating general practice

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Total final enrolment

128

Key exclusion criteria

1. A PSA ≥ 20 ng/ml (indication of prostate cancer or prostatitis)
2. History of allergic reactions to green tea or lycopene containing products (including guava, watermelon)
3. Concurrent medication with finasteride or dutasteride (elevates PSA values)

Date of first enrolment

01/04/2009

Date of final enrolment

30/09/2010

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Bristol University

Bristol

United Kingdom

BS8 2PS

Sponsor information**Organisation**

University of Bristol (UK)

ROR

<https://ror.org/0524sp257>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (ref: C11046/A10052)

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|--------------------------------|--------------|------------|----------------|-----------------|
| Results article | nested interview study results | 03/05/2014 | | Yes | No |
| Results article | nested interview study results | 05/11/2014 | | Yes | No |
| Results article | results | 15/04/2019 | 11/07/2019 | Yes | No |