Effect of Sulforaphane on prostate CAncer PrEvention (ESCAPE)

Submission date	Recruitment status No longer recruiting	Prospectively registered		
11/10/2013		☐ Protocol		
Registration date 11/10/2013	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
22/06/2021	Cancer			

Plain English summary of protocol

http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-effect-sulforaphane-prostate-cancer-escape

Contact information

Type(s)

Scientific

Contact name

Dr Antonietta Melchini

ORCID ID

https://orcid.org/0000-0001-5256-2724

Contact details

Quadram Institute Bioscience Norwich Research Park Colney United Kingdom NR4 7UA +44 1603 255030 antonietta.melchini@ifr.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)

NCT01950143

Protocol serial number

14482

Study information

Scientific Title

A human dietary intervention study to investigate the effect of sulforaphane on prostate cancer interception

Acronym

ESCAPE

Study objectives

The biology of prostate cancer is associated with changes in genes and metabolites within prostate tissue. There is robust evidence to suggest that isothiocyanates (ITCs), compounds found in broccoli and other cruciferous vegetables, can affect the development of prostate cancer by influencing these changes.

We propose to undertake a dietary intervention study on a group of men with early prostate cancer on active surveillance in order to investigate changes in genes and other measurable compounds in prostate, blood and urine that would reflect the activity of prostate disease. Volunteers recruited onto this study will be randomly allocated to one of three dietary groups in which they will be required to consume two portions of broccoli soup per week, delivering a different concentration of sulforaphane (SF) as part of their normal diet for one year. SF is one of most abundant ITCs found in broccoli and has been proven to have many health promoting properties.

Blood, urine and prostate biopsy tissue will be obtained before and after a 12 month intervention period. Prostate biopsies will be obtained either though transperineal template biopsies, a technique accepted as best clinical practice because it provides better sampling of the prostate or we will use transrectal ultrasound guided biopsy which is currently the standard of care for obtaining biopsies in the NHS.

This study builds upon and extends a successful pilot study of similar design undertaken between 2006 and 2008 (REC Ref: 05/Q0101/9). The proposed study has a similar experimental design but with some important differences to enable acquisition of further information regarding diet and prostate biology.

This study will be funded by Biotechnology and Biological Sciences Research Council (BBSRC) and Prostate Cancer foundation (PCF).

Ethics approval required

Old ethics approval format

Ethics approval(s)

REC NRES Committee East of England-Cambridge South, 25/06/2013, ref: 13/EE/0110

Study design

Randomised interventional trial; Design type: Prevention, Treatment

Primary study design

Interventional

Study type(s)

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Prostate Cancer; Disease: Prostate

Interventions

Current interventions as of 03/05/2017:

ESCAPE is a double-blind, randomised 12 month dietary intervention trial on men with early prostate cancer on active surveillance. The study takes place at the Human Nutrition Unit (HNU) of the Institute of Food Research (IFR) and at the urology clinic at the Norfolk and Norwich University Hospital (NNUH). Participants are asked to attend one visit at the HNU for a talk and three or four visits to the NNUH depending on the technique of prostate biopsy. Participants are randomly allocated to one of three dietary groups in which they will be required to consume one portion of broccoli soup per week, delivering a different concentration of the dietary bioactive sulforaphane (SF) as part of their normal diet for one year. SF is one of most abundant sulfur compound found in broccoli and has been proven to have many health promoting properties. Blood, urine and prostate biopsy tissue will be obtained before and after a 12 month intervention period. Prostate biopsies are obtained either though transperineal template biopsies, a technique accepted as best clinical practice because it provides better sampling of the prostate or using transrectal ultrasound guided biopsy which is currently the standard of care for obtaining biopsies in the NHS.

Previous interventions:

Broccoli soups, Volunteers recruited into this study will be randomly placed in one of three dietary groups in which they will be required to consume two portions of broccoli soup per week, delivering a different level of glucoraphanin (SF precursor), as part of their normal diet for one year.

The three types of soup will contain:

- 1. standard broccoli
- 2. glucoraphanin-enriched broccoli (Beneforte®) (
- 3. Beneforte extra

Beneforte and Beneforte extra broccoli are especially cultivated to deliver high SF.

Study Entry: Single Randomisation only

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Sulforaphane

Primary outcome(s)

Current primary outcome measures as of 03/05/2017:

Global gene expression is measured using prostate tissue samples at baseline and 12 months.

Previous primary outcome measures:

Global gene expression; Timepoints: 12 months post intervention

Key secondary outcome(s))

Current secondary outcome measures as of 03/05/2017:

Metabolite concentration is measured using prostate tissue samples at baseline and 12 months.

Previous secondary outcome measures:

Metabolite concentration; Timepoints: 12 months after intervention

Completion date

31/10/2017

Eligibility

Key inclusion criteria

- 1. Males
- 2. Diagnosed with low and intermediate prostate cancer on active surveillance
- 3. Aged 18-80 years
- 4. Body mass index (BMI) between 19.5 and 35 kg/m2
- 5. Smokers and non-smokers

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

Male

Total final enrolment

49

Key exclusion criteria

- 1. Those undergoing chemopreventive therapy
- 2. Those regularly taking 5a-reductase inhibitors or testosterone replacement medicines
- 3. Those on warfarin treatment
- 4. Those diagnosed with diabetes
- 5. Those diagnosed with or suspected to be high-risk for HIV and/or hepatitis
- 6. Those allergic to any of the ingredients of the broccoli soups
- 7. Those taking dietary supplements or herbal remedies which may affect the study outcome unless the volunteer is willing to discontinue taking them for 1 month prior to starting study. Please note that some supplements may not affect the study and this will be assessed on an

individual basis

- 8. Parallel participation in another research project which involves dietary intervention
- 9. Any person related to or living with any member of the study team

Date of first enrolment

29/07/2013

Date of final enrolment

31/10/2016

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Norfolk and Norwich University Hospital

Colney Lane Norwich Colney United Kingdom NR4 7UA

Sponsor information

Organisation

Quadram Institute Bioscience

ROR

https://ror.org/04td3ys19

Funder(s)

Funder type

Charity

Funder Name

Prostate Cancer Foundation (UK)

Alternative Name(s)

CaP CURE, PCF

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Funder Name

Biotechnology and Biological Sciences Research Council (BBSRC) (UK)

Alternative Name(s)

UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, Biotechnology and Biological Sciences Research Council (BBSRC), BBSRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2019	13/08/2019	Yes	No
HRA research summary	Participant information sheet		28/06/2023		No
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Plain English results			22/06/2021	No	Yes