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Effect of Sulforaphane on prostate CAncer PrEvention (ESCAPE)

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01950143

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
31/01/2013

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Male

Target number of participants
UK Sample Size: 100

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
England

United Kingdom

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
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Sponsor information

Organisation
Quadram Institute Bioscience

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Sponsor type
Research organisation

Website
www.quadram.ac.uk

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, BBSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/10/2018

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
Not provided at time of registration

Study outputs

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