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UK PREvention of Cancer by Intervention with SElenium

Submission date 18/05/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/05/2001	**Overall study status** Completed	
Last Edited 02/02/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00022165

Study information

Scientific Title
UK PREvention of Cancer by Intervention with SElenium: a pilot randomised controlled feasibility study

Acronym
UK PRECISE Pilot Study

Study objectives
The PRECISE trial aims to show not only whether selenium has a protective effect against cancer, but also how much selenium is needed to have this effect and which people will benefit most.

Added as of 27/03/2009: Please note that the main trial never started due to lack of funding. The pilot study was successfully completed, and the pilot trial information was added to this record on 12/07/2010. All changes can be found below in the relevant section with the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 13/07/2010:
1. South Tees Research Ethics Committee approved on the 1st February 2000 (ref: 99/69)
2. Worcestershire Health Authority Local Research Ethics Committee approved on the 17th March 2000 (ref: LREC 74/99)
3. Norwich District Research Ethics Committee approved on the 9th December 1999 (ref: LREC 99 /141)
4. Great Yarmouth and Waveney LREC approved on the 22nd February 2000 (under reciprocal arrangements with Norwich District LREC)

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Multiple cancer sites

Interventions
Current information as of 12/07/2010:
Participants receive either a 100 µg, 200 µg, 300 µg selenium as selenium-enriched yeast supplement or a placebo yeast supplement every day for six months. Follow-up was for a minimum of six months (we had hoped this pilot would lead into the main trial phase).

Previous information at time of registration:
Participants receive either a 100 µg, 200 µg, 300 µg selenium supplement or a placebo every day.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Selenium

Primary outcome(s)
Added 12/07/2010:
This was a feasibility study to show the ability to run the main trial.

Key secondary outcome(s)
Added 12/07/2010:
1. Mood (Profile of Mood States Bi-Polar Form [POMS-BI]), measured at baseline and 6 months
2. Quality of life (36-item Short Form Health Survey [SF-36]), measured at baseline and 6 months
3. Thyroid function (thyroid stimulating hormone [TSH], total and free T4 and T3), measured at baseline and six months

Completion date
31/12/2002

Eligibility

Key inclusion criteria
Volunteers aged 60 - 74 years old, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
Added 12/07/2010:
1. Southwest Oncology Group (SWOG) grading scale performance status score greater than 1 or equivalent
2. Active liver or kidney disease (known abnormal liver or kidney function)
3. Prior diagnosis of cancer (excluding non-melanoma skin cancer)
4. Diagnosed human immunodeficiency virus (HIV) infection
5. Diminished mental capacity (subjects must be able to give informed consent to participate as defined by ethics committees)
6. Taking 50 µg/day or more of selenium supplements

Date of first enrolment
01/01/2000

Date of final enrolment

31/12/2002

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Faculty of Health and Medical Sciences
Guildford
United Kingdom
GU2 5XH

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research Campaign (UK) - funded a pilot trial for this study, completed in 2002

Results and Publications

Individual participant data (IPD) sharing plan

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	selenium supplementation, mood and quality of life results	15/01/2006		Yes	No
Results article	selenium supplementation and thyroid function results	01/02/2008		Yes	No
Results article	high-selenium yeast on plasma lipids results	17/05/2011		Yes	No
Other publications	supplementation with selenium does not affect total homocysteine concentration in the UK elderly population:	01/11/2008		Yes	No