ISRCTN64336220 https://doi.org/10.1186/ISRCTN64336220

A randomised double-blind placebo-controlled cancer prevention trial with an estimated duration of 5 years and with 52,000 subjects recruited from the general populations of the UK, Denmark, Sweden, Finland and the United States

Submission date 01/07/2001	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 01/07/2001	**Overall study status** Stopped	
Last Edited 15/11/2013	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PRECISE

Study information

Scientific Title

Study objectives
Not provided at time of registration

Added as of 27/03/2009: Please note that this trial never started due to lack of funding.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double-blind placebo-controlled

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Interventions
Four treatment groups:
1. Placebo
2. 100 micrograms selenium/day
3. 200 micrograms selenium/day
4. 300 micrograms selenium/day

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1995

Completion date
29/06/2001

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
All those aged between 60 and 74 years are eligible.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
52,000

Key exclusion criteria
1. Southwest Oncology Group (SWOG) performance status score of greater then 1 or equivalent
2. Active liver or kidney disease
3. Prior diagnosis of cancer
4. Diagnosed Human Immunodeficiency Virus (HIV) infection
5. Disminished mental capacity
6. Taking 50 micrograms/day or more of selenium supplements

Date of first enrolment
01/01/1995

Date of final enrolment
29/06/2001

Locations

Countries of recruitment
Denmark

England

Finland

Sweden

United Kingdom

United States of America

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
United Kingdom
WC2A 3PX
+44 (0)207 317 5186
kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration