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

Plain English summary of protocolNot provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr--

Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

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