# Bladder Cancer Prognosis Programme (incorporating SELENIB trial)

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
12/04/2006		Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
24/05/2006		[X] Results		
Last Edited	Condition category	[] Individual participant data		
02/11/2023	Cancer			

# Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-risk-factors-for-bladder-cancer-coming-back

# Study website

http://www.bcpp.bham.ac.uk

# **Contact information**

# Type(s)

Principal Investigator

### Contact name

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

NCT00553215

Secondary identifying numbers

BCPP 2005-01

# Study information

### Scientific Title

Bladder Cancer Prognosis Programme (incorporating SELENIB trial)

### Acronym

**BCPP, SELENIB** 

# Study objectives

Objectives:

- 1. To assess the effect of lifestyle factors (such as smoking, dietary habits, fluid intake and environmental exposures) on the recurrence and progression of bladder cancer
- 2. To investigate whether selenium and/or vitamin E (aplha-tocopherol) supplementation reduces the risk of recurrence and progression of superficial bladder cancer
- 3. To study health-related quality of life and its association with recurrence and progression of bladder cancer
- 4. To establish a bladder cancer tissue bank (that will comprise of blood, urine, and bladder tissue)
- 5. To study the predictive effect of molecular markers on the recurrence and progression of bladder cancer

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Nottingham Research Ethics Committee (REC) 2, October 2005, ref: 05/Q2404/173

# Study design

Double-blinded placebo-controlled 2 x 2 factorial randomized controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Not specified

# Study type(s)

Prevention

# Participant information sheet

http://www.bcpp.bham.ac.uk/PatientInfoSheets-v1.pdf

# Health condition(s) or problem(s) studied

BCPP - bladder cancer (superficial and invasive); SELENIB - superficial bladder cancer

### **Interventions**

Patients are randomised to receive one of the following:

- 1. Selenium and vitamin E placebo
- 2. Selenium placebo and vitamin E (alpha-tocopherol)
- 3. Selenium and vitamin E (alpha-tocopherol)
- 4. Selenium placebo and vitamin E placebo

### Intervention Type

Supplement

### **Phase**

**Not Specified** 

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

Selenium, vitamin E (aplha-tocopherol

### Primary outcome measure

SELENIB trial - primary outcomes

- 1. Recurrence-free interval
- 2. Progression-free interval

Progression is defined as a recurrence with:

- 1. An increase in grade from grade 1/grade 2 to grade 3
- 2. An increase in tumour, node, metastasis (TNM) stage
- 3. The new occurrence of carcinoma in situ (CIS) in a bladder previously free from such lesions
- 4. The new occurrence of multiple urothelial tumours following resection of a solitary urothelial tumour
- 5. The need for a cystectomy because of refractory disease

### Secondary outcome measures

SELENIB trial - secondary outcomes

- 1. All cause mortality
- 2. Incidence of transitional cell carcinoma (TCC) outside the bladder we expect pathological confirmation will be available in most cases but a diagnosis based on strong clinical, radiological and cytological evidence will be acceptable
- 3. Incidence of all other malignancies clinically diagnosed they may be pathologically confirmed or diagnosed based on strong clinical, radiological, laboratory marker or cytological evidence
- 4. Incidence of cardiovascular events:
- a. Myocardial infarction the patient must have symptoms meeting World Health Organization (WHO) criteria and the event associated with abnormal levels of cardiac enzymes or diagnostic electrocardiograms (ECGs)b. Stroke the patient must have a new neurological deficit of sudden onset that has persisted for more than 24 hours or until death within 24 hours
- c. Death from cardiovascular causes this will be confirmed by autopsy reports, death certificates or medical records
- 5. Quality of life as assessed by the quality of life instruments: European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30, QLQ-BLS24 and QLQ-BLM30

# Overall study start date

01/06/2006

# Completion date

01/06/2014

# **Eligibility**

Key inclusion criteria

Inclusion criteria for SELENIB Trial:

- 1. Able to give informed consent for SELENIB
- 2. Previously registered onto the Bladder Cancer Prognosis Programme
- 3. Disease characteristics: histopathologically confirmed non-muscle invasive transitional cell carcinoma. Solitary grade 1 pTa larger than 3 cm and all other stage pTa, pT1 or pTcis

# Participant type(s)

Patient

### Age group

Adult

#### Sex

Both

# Target number of participants

2700 (At time of registration: BCPP-3400 patients, of which 1200 patients randomised to SELENIB)

### Total final enrolment

270

# Key exclusion criteria

Exclusion criteria for SELENIB trial:

- 1. Disease characteristics solitary grade 1 pTa <3 cm or stage pT2 and above
- 2. Patients that are pregnant or breastfeeding
- 3. Patients diagnosed with human immunodeficiency virus (HIV) infection
- 4. Patients who are on immunosuppressive therapy following organ transplantion
- 5. Patients taking cyclosporin
- 6. Any condition, which, in the opinion of the local investigator, might interfere with the safety of the patient or evaluation of the trial objectives

### Date of first enrolment

01/06/2006

### Date of final enrolment

01/06/2014

# Locations

### Countries of recruitment

England

United Kingdom

# Study participating centre The Public Health Building Birmingham

# Sponsor information

### Organisation

University of Birmingham (United Kingdom)

### Sponsor details

Research and Enterprise Services University of Birmingham Edgbaston Birmingham England United Kingdom B15 2TT

### Sponsor type

University/education

### Website

http://www.bham.ac.uk

### **ROR**

https://ror.org/03angcq70

# Funder(s)

# Funder type

Charity

### **Funder Name**

Cancer Research UK (C1343/A5738)

### Alternative Name(s)

CR\_UK, Cancer Research UK - London, CRUK

# **Funding Body Type**

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

# **Results and Publications**

# Publication and dissemination plan

Current publication and dissemination plan as of 23/03/2023: Planned publication in a high-impact peer-reviewed journal

Previous publication and dissemination plan: Not provided at time of registration

# Intention to publish date

22/08/2023

# Individual participant data (IPD) sharing plan

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

# IPD sharing plan summary

Data sharing statement to be made available at a later date

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results	BCPP			No	Yes
Results article		02/10/2023	23/10/2023	Yes	No
Plain English results	SELENIB		02/11/2023	No	Yes