ISRCTN13889738 https://doi.org/10.1186/ISRCTN13889738

Bladder Cancer Prognosis Programme (incorporating SELENIB trial)

Submission date	Recruitment status	[X] Prospectively registered
12/04/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/05/2006	Completed	[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

Contact information

Type(s)
Principal investigator

Contact name
Prof Richard Bryan

ORCID ID
https://orcid.org/0000-0003-2853-4293

Contact details
Institute of Cancer and Genomic Sciences
Robert Aitken Institute for Clinical Research
College of Medical and Dental Sciences
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 (0)121 414 7870
r.t.bryan@bham.ac.uk

Type(s)
Scientific

Contact name
Prof Richard Bryan

Contact details
Institute of Cancer and Genomic Sciences
Robert Aitken Institute for Clinical Research
College of Medical and Dental Sciences
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 (0)121 414 7870
r.t.bryan@bham.ac.uk

Type(s)
Public

Contact name
Mr Ben Abbotts

Contact details
BCPP/SELENIB Trial Coordinator
POUT-T Trial Coordinator
Institute of Cancer and Genomic Sciences
Room G26, RAICR
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 (0)121 415 8836
b.abbotts@bham.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00553215

Protocol serial number
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

Study type(s)
Prevention

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
The Public Health Building
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (United Kingdom)

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, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

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?
Results article		02/10/2023	23/10/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results	BCPP			No	Yes
Plain English results	SELENIB		02/11/2023	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes