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

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

Contact information

Type(s)
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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

United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (United Kingdom)

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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

United Kingdom

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