The effect of dietary and lifestyle factors on prognosis and quality of life of bladder cancer patients

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The purpose of this study is to answer the following research questions:1. What are the dietary and lifestyle habits (with a focus on, but not restricted to, fluid intake, fruit and vegetable consumption, and smoking) of NMIBC patients before...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON38950

Source
ToetsingOnline

Brief title
UroLife

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
bladder cancer, urothelial cell cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Alpe d'HuZes / KWF Kankerbestrijding

Intervention

Keyword: bladder cancer, lifestyle, prognosis, quality of life

Outcome measures

Primary outcome

The main study parameters are fluid intake, fruit and vegetable consumption,

smoking, biomarkers of fruit and vegetable consumption, and cotinine.

The main study endpoint is NMIBC recurrence.

Secondary outcome

Secondary study parameters are other dietary and lifestyle factors.

Secondary study endpoints are NMIBC progression and health-related quality of

life (HRQOL).

Study description

Background summary

Bladder cancer is the fourth most common cancer among men and the eighth most common cancer among women in the Netherlands, with 6,019 men and women diagnosed in 2010. About 70% of bladder cancer patients present with non-muscle-invasive bladder cancer (NMIBC). These patients have a relatively good survival, but are at high risk of tumor recurrence and disease progression (approximately 60% and 15% within 5 years, respectively). They are therefore subjected to frequent follow-up by cystoscopy and treatment. This makes bladder cancer the most expensive cancer in terms of health care expenditures. The frequent recurrences may also impact greatly on health-related quality of life (HRQOL). Thus, it is important to identify prognostic factors that may enable to reduce the risk of frequent recurrence(s) and progression, and improve HRQOL. Dietary and lifestyle factors may play an important role in bladder cancer prognosis. A high fluid intake reduces the exposure to carcinogens by diluting the urine and reducing the contact time through increased frequency of micturition. Most dietary substances and metabolites are excreted by the urinary tract, and fruit and vegetables are a rich source of nutrients with anticancer properties. Smoking is the most important lifestyle factor associated with bladder cancer, and smoking cessation decreases the risk.

However, there is only sparse data on the association between (changes in) dietary and lifestyle habits and bladder cancer prognosis and HRQOL. Further, it is unclear to which degree bladder cancer patients are adhering to dietary and lifestyle guidelines for cancer survivors, which is an important first step in promoting healthy lifestyle behavior.
Thus, there is an urgent need to gain insight in the dietary and lifestyle habits of bladder cancer patients in order to develop effective dietary and lifestyle interventions to reduce their risk of recurrence/progression and to improve their HRQOL.

Study objective

The purpose of this study is to answer the following research questions:
1. What are the dietary and lifestyle habits (with a focus on, but not restricted to, fluid intake, fruit and vegetable consumption, and smoking) of NMIBC patients before diagnosis of cancer, do they change these habits after diagnosis, and to what extent do they adhere to the existing dietary and lifestyle guidelines for cancer survivors at both time points?
2. Are pre- and postdiagnosis dietary and lifestyle habits, as well as changes in these habits, associated with the risk of recurrence and progression of NMIBC?
3. What is the burden imposed by NMIBC upon patient HRQOL, and does this change during the course of the disease?
4. Are pre- and postdiagnosis dietary and lifestyle habits, as well as changes in these habits, associated with HRQOL?
5. Are NMIBC patients aware of, do they currently receive, or would they be interested in receiving information about dietary and lifestyle factors that may improve their prognosis?

Study design

Prospective cohort study. At inclusion shortly after first transurethral resection, dietary and lifestyle habits before diagnosis as well as HRQOL will be assessed by questionnaire. At first routine follow-up approximately three months after transurethral resection, and 15 months after transurethral resection, changes in dietary and lifestyle habits and HRQOL will be assessed. At three and 15 months after transurethral resection, blood samples will be collected in which biomarkers of fruit and vegetable intake will be assessed as well as cotinine as a compliance marker for smoking cessation in ex-smokers. Information about therapy, disease characteristics and additional medications will be derived from medical records and taken into account in the analyses. In addition, a survey will be conducted to investigate the awareness and the type of information bladder cancer patients currently receive and/or would like to receive from their urologist concerning diet and lifestyle.

Study burden and risks

Risks associated with participation in this cohort are confined to the normal risks of taking blood samples (risk of fainting and of bruising). Since the drawing of blood will be done by professionals, risks are low. The only burden for participants is, that they are asked to fill out questionnaires shortly, three months, and 15 months after diagnosisabout, and that they are asked to donate blood samples three and 15 months after diagnosis. Blood collection is aimed to be at the same time as the regular follow-up appointment in the hospital.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- First, primary non-muscle-invasive bladder cancer (T0, T1, Tis)
- Diagnosis between 01-01-2014 and 01-07-2016

- Aware of diagnosis
- Between 18 and 80 years at diagnosis
- Able to communicate in Dutch, and read and understand the patient information and informed consent form
- Able to fill out questionnaires

Exclusion criteria

- Previous diagnosis with other cancers within last 5 years
- >=N1, M1 (if known)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-05-2014
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO Date:	17-01-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-05-2014

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-07-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-09-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-10-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-12-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-01-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-04-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-05-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-06-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-07-2015

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-10-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-02-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-05-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-08-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-09-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL44364.091.13