BlaaskankerZorg In Beeld

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26633

Source
Nationaal Trial Register

Brief title
BlaZIB

Health condition

Bladder cancer

Sponsors and support

Primary sponsor: Dutch Cancer Society (KWF Kankerbestrijding)
Source(s) of monetary or material Support: Dutch Cancer Society; grant number IKNL 2015-7914

Intervention

Outcome measures

Primary outcome

Oncological outcomes (disease recurrence, progression, mortality, disease-free survival and overall survival) and Health-related quality of life

Secondary outcome

Complications, toxicity, complete pathological response, downstaging

Study description

Background summary

Background: Even though there are European guidelines for bladder cancer management, there is still large variation in the applied diagnostics and treatments in clinical practice. This variation may affect patients' clinical outcomes like complications, disease recurrence- and progression and survival but also health-related quality of life (HRQL). Lack of detailed clinical data and absence of HRQL data hampers a comprehensive evaluation of bladder cancer care. The purpose of the current study is to provide insight in bladder cancer care and to identify barriers and supporting factors for optimal care in order to improve bladder cancer care.

Methods: This study is a nationwide prospective cohort study including all patients newly diagnosed with high-risk non-muscle invasive bladder cancer (HR-NMIBC; CIS and T1) or muscle invasive bladder cancer (MIBC; ≥T2) between November 1st 2017 and end 2019 in the Netherlands. Extensive data concerning patient- and tumor characteristics, diagnostics, treatment and follow-up until 2 years after diagnosis will be prospectively collected from the electronic health records in the hospitals by data managers of the Netherlands Cancer Registry (NCR). In addition, patients will be asked to fill out an online HRQL questionnaire shortly after diagnosis and 6, 12 and 24 months after diagnosis. The questionnaire on HRQL includes five standardized questionnaires, e.g. EQ-5D-5L, EORTC-QLQ-C30, EORTC-QLQ-BLM30, EORTC-QLQ-NMIBC24 and BCI. Descriptive analyses and multivariable multilevel analyses will be performed to assess variation in care and to identify factors underlying this variation. Survival analyses will be used to relate variation in care to relevant outcomes such as survival.

Discussion: This study will evaluate usage of (inter)national guidelines, identify reasons for practice variation and obstacles for optimal quality of bladder cancer care. The results from this project can set the agenda for specific research questions in the management of bladder cancer and may lead to adaptation of clinical practice and/or guidelines

Study objective

NA

Study design

Clinical data are collected at two moments in time: 6 months and 2 year after diagnosis. HRQL questionnaires are sent 6 weeks, 6 months, 1 year and 2 year after diagnosis.

Intervention

NA

Contacts

Public
Netherlands Comprehensive Cancer Organisation
Katja Aben

+31646146854
Scientific
Netherlands Comprehensive Cancer Organisation
Katja Aben

+31646146854

Eligibility criteria

Inclusion criteria

All newly diagnosed Dutch patients with High-Risk Non-Muscle Invasive Bladder Cancer (HR-NMIB; Cis and T1) and Muscle invasive Bladder Cancer (MIBC; ≥T2) between November 1st 2017 and end 2019 in the Netherlands.

Exclusion criteria

NA

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2017
Enrollment:	6500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
All data collected within BlaZIB are integrated in the Netherlands Cancer Registry (NCR) held by the Netherlands Comprehensive Cancer Organisation (IKNL). One year after completion of the study, data will be available for clinical and scientific research questions. All data requests are reviewed by the supervisory committee of the NCR for compliance with the NCR/IKNL objectives and (inter)national (privacy) regulation and legislation. For more information about these conditions, please visit: https://www.cijfersoverkanker.nl/algemene-voorwaarden-61.html

Ethics review

Positive opinion

Date:	22-10-2019
Application type:	First submission

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
NTR-new	NL8106
Other	CMO Arnhem-Nijmegen : 2017.3240

Study results