Health status and burden of late effects in very long-term testicular cancer survivors.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON47425

Source
ToetsingOnline

Brief title
STANDBY-study

Condition

- Reproductive neoplasms male malignant and unspecified
- Renal disorders (excl nephropathies)

Synonym
testicular cancer, testicular germ cell tumour

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: KWF subsidie (RUG2011-5267)

Intervention

Keyword: Late adverse treatment effects, Renal function, Survivorship, Testicular cancer

Outcome measures

Primary outcome

Primary study parameters are is renal function as expressed by glomerular filtration rate (GFR).

Secondary outcome

Secondary parameters are the prevalence of the following defined adverse late effects: CVD, peripheral neuropathy, reduced lung function, Raynaud*s phenomenon, hypogonadism, fatigue and cognitive dysfunction. Other secondary parameters are health related quality of life (HRQoL), physical fitness, markers for (subclinical) vascular damage, single nucleotide polymorphisms (SNPs) and aging markers (telomere length in DNA and arterial stiffness).

Study description

Background summary

Depending on disease stage, testicular cancer (TC) treatment consists of an orchidectomy, alone or followed by radiotherapy (RT) or platinum-based chemotherapy (CT). TC survival rates are above 90% nowadays, which results in growing TC survivor population. Because of the long life expectancy of these survivors, prevention or early detection of late treatment effects has become increasingly relevant. Yet known late effects are nephrotoxicity, cardiovascular disease (CVD), secondary malignant neoplasms (SMN), neurotoxicity, pulmonary toxicity, Raynaud*s phenomenon, hypogonadism, fatigue and psychosocial problems. Nephrotoxicity is an important late effect, but data is lacking in very long-term survivors, since performed studies have a follow-up duration of 5-14 years. Decreased renal function is a known risk factor for CVD development and also an association between renal function and neurotoxicity via circulating platinum levels has been shown. We hypothesize that treatment induced nephrotoxicity is prevalent in TC survivors and might be

a mediator for development of late effects. Our secondary aim is to assess prevalence of late effects in very long-term TC survivors: until now, most data have been collected through questionnaires in large epidemiological studies in TC survivors till approximately 10 years after treatment. The prevalence of late effects may increase over time: 10 years after treatment late effects may not be present yet, whilst late effects can emerge just after 20 years. Consequently, health status and possible late effects, resulting in morbidity, are underestimated in patients who are 20-30 years after treatment. By investigating health status of these very long-term survivors a more profound insight in the prevalence and aetiology of these late effects and the development over time can be assessed. Current treatment is very similar to TC treatment 20-30 years ago and therefore knowledge on late effects is relevant for currently treated patients. Furthermore, as a result of this study, we will better understand which factors and issues should be watched closely during follow-up, which TC survivors are at increased risk of developing late treatment effects and how to detect early damage before overt morbidity occurs.

Study objective

The aim of this study is to compare glomerular filtration rate (GFR) in very long-term TC-survivors treated with chemotherapy, radiotherapy or surgery only and non-cancer treated healthy controls. Furthermore, a secondary aim is to assess prevalence of adverse late treatment effects in very long-term TC-survivors treated with CT, RT or surgery only and investigate the relationship between GFR parameters and these late effects.

Study design

We will perform an observational cross-sectional cohort study. Patients will be invited for a single study visit, which consists of collection of urine during 24 hours, withdrawal of blood samples, filling in questionnaires, physical examination, vascular function and structure tests, lung function tests, digital cooling tests, neuropsychological assessment and a walk test.

Study burden and risks

Participants are asked to bring a single study visit of approximately three hours. Venapuncture is the only invasive procedure, with low risk of adverse effects. By inviting survivors who are not in any routine follow-up care, research into late effects and risk factors can be combined with lifestyle counselling regarding cardiovascular risk reduction. More knowledge about late effects of TC treatment can lead to better prevention and earlier detection of these late effects and to development of new follow-up strategies.

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

Three groups of TC survivors will be included: treated with surgery and chemotherapy (CT group), surgery and radiotherapy (RT group) or surgery only (SU group). We also will include a control group (CO group) of healthy volunteers who have not been treated for any type of cancer. The groups will be age matched with te patients from the CT group, a margin of three years will be accepted.;Inclusion criteria for both TC survivors as controls:
1. Age <70 years at time of inclusion
2. Signed informed consent;Additional inclusion criteria for CT-group:
3. Patients treated with cisplatin-based chemotherapy for TC good or intermediate IGCCCG prognosis.
4. Age at start of TC treatment <40 yrs.
5. At least 20 years after start of treatment for TC at time of inclusion.;Additional inclusion criteria for RT-group:

3. Patients treated with radiotherapy for TC stage I or II.
4. Age at start of TC treatment < 40 yrs.
5. At least 20 years after start of treatment for TC at time of inclusion.;Additional inclusion criteria for SU- group:
3. Patients treated with orchidectomy only for TC stage I.
4. Age at start of TC treatment < 40 yrs.
5. At least 20 years after start of treatment for TC at time of inclusion.

Exclusion criteria

Exclusion criteria for both TC survivors as controls:
1. Mental disability (no informed consent available).;Additional exclusion criteria for CT-group:
2. Patients also treated with radiotherapy for TC.;Additional exclusion criteria for RT-group:
2. Patients also treated with chemotherapy for TC.;Additional exclusion criteria for SU-group:
2. Patients also treated with chemo- or radiotherapy for TC.;Additional exclusion criteria for CO-group:
2. Treated with chemotherapy, radiotherapy or hormonal therapy for any type of cancer.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-08-2015
Enrollment:	280
Type:	Actual

Ethics review

Approved WMO Date:	06-08-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-11-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT02572934
CCMO	NL53126.042.15