Living with sarcoma

No registrations found.

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

Summary

ID

NL-OMON28169

Source
NTR

Health condition

Sarcoma, cancer, survivorship, rare cancer.
Sarcomen, kaker, overlevers, zeldzame kanker.

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Radboudumc, profiles registry

Intervention

Outcome measures

Primary outcome

• The health-related quality of life of sarcoma survivors (compared to age- and sex-matched normative population)

Secondary outcome

• Defining risk factors for a worse quality of life (compared to normative population): demographics, time to diagnosis and therapy, clinical characteristics (such as tumour type and site, type of treatment, progression/recurrence of disease), ability to work, financial difficulties, social support, psychological distress, information provision, body image,

sexuality, ability to perform certain tasks (e.g. brush teeth, do groceries)

• Assessing the body image (compared to normative population)

• Assessing the psychological distress (compared to normative population)

• Examining the level of certain symptoms (such as pain, fatigue, nausea)

• Difference in HRQoL, body image, psychological distress, level of symptoms with regards to time since diagnosis

• Assessing satisfaction with follow-up schedule

• Assessing difficulties sarcoma patients encounter due to the rarity of the disease

Study description

Background summary

Background

Patients with sarcoma belong to the group of so-called rare cancer patients. When taken all sarcoma patients together they are responsible for 1-2 % of all cancer diagnoses in adults 1. Sarcomas are heterogeneous in many aspects: first of all there are more than 70 histological subtypes, second the genetic background is extremely different between sarcoma subtypes and even within subtypes, and lastly, the phenotype of sarcomas is heterogeneous, starting with the age range of incidence between 0 and 100 years and the localisation anywhere in the body 1. In 2015, 973 people were newly diagnosed with sarcoma (70% soft tissue sarcoma, 21% bone, 5% Kaposi sarcoma, 3% neuroblastoma, 1% paraganglioma; www.cijfersoverkanker.nl) in The Netherlands.

Due to the rarity of the disease, diagnosis is frequently delayed. This results from a lack of public awareness of sarcoma symptoms, coupled with limited experience among healthcare professionals 2. Approximately one third of patients present with advanced disease, not amenable to curative surgical resection. In addition, sarcomas generally demonstrate an aggressive phenotype and around 50% of patients will eventually develop incurable metastatic disease 3, 4. The five-year overall survival (period 2008-2012) is 80% for bone sarcoma and 63% for soft tissue sarcoma (www.cijfersoverkanker.nl), however these must be interpreted in the context of significant heterogeneity.

Although the clinical effectiveness of treatments has improved in the past years, the corresponding toxicity and the varying degrees of long-lasting and cumulative treatment side-effects in many patients contribute to the overall limited advantages. Therefore, it is important to assess treatment effectiveness both in terms of objective outcomes (e.g., progression-free or overall survival) and in terms of subjective Patient Reported Outcomes (PROs). Measuring PROs includes the assessment of health-related quality of life (HRQoL)5 as well as illness-related symptoms such as pain or fatigue.

Overall HRQoL data in sarcoma patients are lacking, probably due to the fact that it can be difficult to follow-up patients prospectively. A recent Sarcoma Patient Experience Survey run by Sarcoma UK with more than 500 participants showed that sarcoma patients report “experienced” health care services that are much lower than patients with some form of common cancer. Data from this survey showed delayed diagnoses and referrals to sarcoma centres, a lack of adequate emotional support, and lack of referrals to support groups, lack of clinical trial participation in the elderly and lack of referrals to rehabilitation services in the elderly. Of all participating patients 41% reported pain, 48% fatigue and 37% nerve sensations or numbness. However, the data were not collected in a systematic way and no internationally validated questionnaires were used.

To address the lack of robust and meaningful HRQoL data we will conduct a multi-institutional cross-sectional cohort study to assess HRQoL among sarcoma survivors. Results of this study will ultimately help to optimize the sarcoma patient journey by improving individual management decisions, tailoring treatments to a specific patient, and development of supportive care services.

Objectives

In this study we aim to gain insight into the HRQoL, symptoms and care needs of a population-based sample of sarcoma patients. We will do this by:

1) Examining the levels of HRQoL and prevalence of symptoms

2) Comparing the HRQoL and symptoms of sarcoma patients with an age- and sex-matched normative population

3) Assessing socio-demographic (e.g. age, sex, educational level), clinical (sarcoma subtype, treatment, co-morbidity et cetera), health care (e.g. health access, information provision, satisfaction with care, diagnostic and therapeutic pathway) and psychological (e.g. social support, handling concerns, illness cognition, psychological distress) characteristics

associated with HRQoL, symptoms and care needs.

Primary endpoint

• The health-related quality of life of sarcoma survivors (compared to age- and sex-matched normative population)

Secondary endpoints

• Defining risk factors for a worse quality of life (compared to normative population): demographics, time to diagnosis and therapy, clinical characteristics (such as tumour type and site, type of treatment, progression/recurrence of disease), ability to work, financial difficulties, social support, psychological distress, information provision, body image, sexuality, ability to perform certain tasks (e.g. brush teeth, do groceries)

• Assessing the body image (compared to normative population)

• Assessing the psychological distress (compared to normative population)

• Examining the level of certain symptoms (such as pain, fatigue, nausea)

• Difference in HRQoL, body image, psychological distress, level of symptoms with regards to time since diagnosis

• Assessing satisfaction with follow-up schedule

• Assessing difficulties sarcoma patients encounter due to the rarity of the disease

Study design and methodology

A cross-sectional population-based cohort study will be conducted among all sarcoma patients registered in the Netherlands Cancer Registry (NCR). The NCR records data on all patients who are newly diagnosed with cancer in the Netherlands. The NCR will be used to select all sarcoma patient who were diagnosed with sarcoma (according to the ICD-10-GM codes C40 and C41 for bone sarcoma and C49 for soft-tissue sarcoma), between 1/1/2008 and 31/12/2016. Only patients diagnosed or treated within one of the participating - in sarcoma specialized - study centres (Radboud University Medical Centre Nijmegen, Erasmus Medical Centre Rotterdam, University Medical Centre Leiden, Netherlands Cancer Institute Amsterdam, University Medical Centre Groningen, Maastricht University Medical Centre) will

be selected.

In order to be eligible to participate in this study, a subject must be 18 years or older at time of diagnosis. Patients who have cognitive impairment or are too ill at time of the study (according to advice from (former) treating specialist) or died prior to the start of the study (according to data from the hospital of diagnosis and/or data from the Dutch municipal personal records database) will be excluded. In addition, patients with desmoid fibromatosis will be excluded because of the non-malignancy of the disease; and patients with gastrointestinal stromal tumours (GIST; ICD-10-GM codes C15-20, C26, C48, and C80) will be excluded because they are included in another Dutch study (from NKI-AVL).

Questionnaire administration will be done within the PROFILES registry (Patient Reported Outcomes Following Initial treatment and Long term Evaluation of Survivorship; www.profilesregistry.nl)6. PROFILES is a data management system set up in 2009 in The Netherlands for the study of the physical and psychosocial impact of cancer and its treatment. PROFILES contains a large web-based component and is linked directly to clinical data from the cancer registry.

Eligible patients will receive an invitation package from their (ex-)treating healthcare professional. The invitation package consists of a letter and a patient information sheet. The patient information sheet explains the goals and procedure of the study. It includes a link to a secure website (www.profielstudie.nl), a login name, and a password, so that interested patients can provide informed consent (by initial boxes) and complete questionnaires online. The login codes are not directly linked to the patient. Patients are assured that non-participation has no consequences for their treatment or follow-up care. If the patient does not have access to internet, or prefers written rather than digital communication, (s)he will receive a paper version of the questionnaire package.

Study objective

Examining the levels of HRQoL and prevalence of symptoms of sarcoma survivors

Study design

Not applicable.

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

-Diagnosis of sarcoma sarcoma (according to the ICD-10-GM codes C40 and C41 for bone sarcoma and C49 for soft-tissue sarcoma), between 1/1/2008 and 31/12/2016.

-Diagnosed or treated at one of participating centres (Radboud University Medical Centre Nijmegen, Erasmus Medical Centre Rotterdam, University Medical Centre Leiden, Netherlands Cancer Institute Amsterdam, University Medical Centre Groningen)

-Must be able to complete questionnaire in Dutch

Exclusion criteria

-Cognitive impairment

-Too unwell to complete questionniare

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:	Recruitment stopped
Start date (anticipated):	01-06-2018
Enrollment:	1200
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description
Publishing outcomes in journals

Ethics review

Positive opinion

Date:	28-05-2018
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	NL7048
NTR-old	NTR7253
Other	METC Radboudumc : 2018-4151

Study results