Body image, health-related quality of life, and function after soft tissue sarcoma resection

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Primary objectives : 1- To assess body image, health-related quality of life, self-reported activity limitations, and pain after STS resections as defined in the ICF domains. 2- To assess the functioning of the patients after STS resections as...

Ethical review	Approved WMO
Status	Pending
Health condition type	Musculoskeletal and connective tissue neoplasms
Study type	Observational non invasive

Summary

ID

NL-OMON57021

Source
ToetsingOnline

Brief title
Body image, QoL and functioning after STS resection

Condition

- Musculoskeletal and connective tissue neoplasms
- Soft tissue neoplasms malignant and unspecified
- Soft tissue therapeutic procedures

Synonym
malignant soft tissue tumor, soft tissue sarcomas

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: Universiteit van Amsterdam MD/PhD beurs

Intervention

Keyword: Body image, Functioning, Health-related Quality of life, Soft tissue sarcoma

Outcome measures

Primary outcome

Body image and health-related quality of life (subjective outcomes/endpoints):

- Body image, health-related quality of life, self-reported activity limitations, and pain: Body image will be assessed using the Body Image Scale (BIS).
Health-related quality of life will be assessed using PROMIS-CAT and Eq-5d-5L questionnaires. Pain will be assessed using the numeric rating scale (NRS). These questionnaires will be classified under the ICF domains.

Functioning (objective parameters/endpoints) will be classified under the ICF domains of body functions, body structure, and activities and participation:

Body function:

- Impairments in gait biomechanics will be assessed using 3D gait analysis.
- Impairments in joint function will be determined with a physical examination of both legs and arms on the range of motion , limb circumference, and muscle strength with manual muscle testing (Medical Research Council (MRC)) and a handheld dynamometer. Muscle strength will be also quantified with a Biodex dynamometer (fixed force gauge). Balance and

mobility will be evaluated with 'timed up and go test* (TUG) and *timed up and down stairs* (TUDS).

Body structures:

- Muscle volume change will be evaluated on pre- versus postoperative MRI scans. Additionally, tumor characteristics will be evaluated on preoperative MRI scans.

Activities and participation:

- Objectively measured walking ability will be assessed in terms of walking speed and walking energy cost, as measured during a 6-minute walk test with simultaneous gas analysis.
- Objectively measured balance and mobility by TUG and TUDS test: These tests are part of the physical examination.

Secondary outcome

- The influence of different variables (e.g., gender, ethnicity, education level ....) on body image, health-related quality of life and functioning.

- The differences in outcomes regarding body image, health-related quality of life, and functioning between patients after extremity STS resection with or without radiotherapy.

Study description

Background summary

Soft tissue sarcomas (STS) are a heterogeneous group of mesenchymal tumors, comprising over 50 types, which account for approximately 1% of all adult cancers. Last year, 799 new STS cases were presented in the Netherlands, of which 331 (40%) were localized in the extremities. Approximately 75% of trunk and extremity STS are aggressive and infiltrative (high-grade) tumors. STS has about 60% overall survival and 73% metastasis-free survival at 5 years.

The treatment of high-grade extremity STS consists of a (wide) excision with clear margins with or without (neo-) adjuvant radiotherapy and/or (neo-) adjuvant chemotherapy.The resection margins may influence patients* overall survival, but it also determines their body image and quality of life, especially when limb function must be sacrificed to achieve sufficient resection margins. This causes impairments in body structure and function as well as limitations in activities and participation as defined by the International Classification of Functioning, Disability, and Health (ICF). (Neo-)adjuvant radiotherapy increases the probability of tumor-free margins, resulting in a lower risk of local recurrence. However, radiotherapy is associated with significant side effects (such as wound healing problems, infections, risk of reoperation and lymphatic dysfunction). Recently, a subgroup analysis of patients with high-risk STS showed a survival benefit of (neo-)adjuvant chemotherapy. This benefit should outweigh the disadvantages of chemotherapy. Since convincing evidence for the best treatment (including optimal surgical margins, (neo)adjuvant radiotherapy and chemotherapy) is lacking, decisions should be based not only on oncologic outcome measures (local recurrences and survival), but also on self-perception, quality of life and functioning.

Patients want to know more about their expected recovery, ability to walk and function in daily life, at the time of surviving their malignancy. This is a common question asked at the outpatient clinic with no clear answer. There are some studies on health-related quality of life and functioning after STS resections. However, these studies assessed quality of life with general non-sarcoma-specific questionnaires and did not evaluate function with objective outcome measures. Disease-specific measures to assess the impact of STS and their treatment(s) on patients' quality of life are not yet available. These measures could provide more specific insight into the unique challenges faced by this patient population. The EORTC is currently exploring how to design sarcoma-specific questionnaires. In addition, many sarcoma survivors have body image issues after surgery. However, very little attention has been paid to this aspect.

Regarding objective measurements, the effect of sarcoma treatments on walking was reported in a few small, heterogeneous studies. These studies focused on bone sarcoma patients and showed abnormal gait pattern after sarcoma resections. Robinson et al. described a functional gait score after STS resections, but they did not provide specific information on gait pattern. There is a lack of knowledge about gait pattern and other objective walking-related outcomes after STS resections.

Furthermore, many factors have been identified that may affect health-related quality of life in cancer survivors. For example, in a study with 782 cancer survivors, lower education level, household income and non-white race were correlated with lower physical and mental quality of life. However, no information is available on factors associated with body image and health-related quality of life in survivors of STS.

By assessing body image, health-related quality of life, walking ability, and functioning in daily life after STS resections and evaluating these outcomes with more objective outcome measures (gait, energy expenditure while walking, muscle strength, range of motion, etc.), patients and STS professionals gain a broad understanding of the personalized risks and benefits of STS treatment(s) based on patient age, tumor size, tumor depth, and histology. In addition, identifying factors associated with worse outcomes may help healthcare providers identify patients at risk, leading to appropriate interventions and timely referral.

It is hypothesized that adequate information about body image, health-related quality of life, walking ability and functioning in daily life after STS resections leads to more realistic expectations of treatment outcomes for both patients and STS professionals. It reduces uncertainty about the risks and benefits of STS treatments and optimizes individual patient education and care. More knowledge about these aspects can improve surgical decisions, reconstructive techniques, psychosocial support and rehabilitation for these patients.

Study objective

Primary objectives :

1- To assess body image, health-related quality of life, self-reported activity limitations, and pain after STS resections as defined in the ICF domains.
2- To assess the functioning of the patients after STS resections as defined by the ICF domains of body function, body structure, and activities and participation:

Body function:

a) Evaluate impairments in gait biomechanics.
b) Evaluate impairments in joint function as determined by range of motion and muscle strength.

Body structure:

a) Evaluate muscle volume change on pre- and postoperative MRI scans and correlate these findings with body image, health-related quality of life, activity limitations, and functional impairments.

Activities and participation:

a) Objectify activity limitations by walking speed, and energy cost.
b) Objectify balance and mobility as measured by TUG and TUDS.

Secondary objectives:

1- To identify factors associated with body image, health-related quality of life and functioning in extremity STS survivors.
2- To compare body image, health-related quality of life and functioning between patients who were treated with and without radiotherapy.

Study design

This is a cross-sectional follow-up study. All records of consecutive non-metastatic extremity STS patients that had a surgical resection, between 2010-2021 at the Amsterdam UMC will be evaluated. Survivors will be approached to take part in this study by phone, followed by a letter explaining the study including an informed consent form.

The participants can either fill out the self-reported questionnaires (BIS, PROMIS-CAT, EQ-5D-5L, NRS) at home through the internet (using EPIC/Castor) or on a tablet at the outpatient clinic with the help of the investigator. All self-reported questionnaires used in this study are in Dutch. However, participants can also choose to fill out the questionnaires in another language.

The participants will be asked to visit the outpatient clinic for a physical examination (to assess joint range of motion, limb circumferences, balance and mobility with 'timed up and go test* (TUG) and *timed up and down stairs* (TUDS), isometric muscle strength using hand-held dynamometry, and manual muscle strength (MRC)). Computer-based questionnaires can be completed at the outpatient clinic if not already done at home. This part of the study will be performed at the Department of Orthopedic Surgery and Sports Medicine, Amsterdam UMC, the Netherlands. During the same visit, patients will have a 3D gait analysis (to assess gait biomechanics), muscle strength assessment using a Biodex dynamometer, and a 6-minute walk test (to assess walking speed and

walking energy cost) at the rehabilitation department.

The total study period depends on the time needed for data collection, which will take about one to two years.

Results from the self-reported questionnaires and muscle strength using a Biodex dynamometer will be compared to the general population means. Results on walking speed, walking energy cost, physical examination, and gait biomechanics will be compared within patients (contralateral healthy vs treated limb), between patients after upper extremity and lower extremity STS resection, and to general population means. Results from muscle strength assessment using a Biodex dynamometer will be compared to the contralateral healthy limb. Additionally, the results from the objective functional tests and the MRI-scans (with tumor and pre- plus postoperative muscle specific features) will be correlated with body image and health-related quality of life questionnaires

Study burden and risks

The risks of participating in this study are negligible. The tests used in this study have no serious side effects. The burden is also minimal. Patients need to visit the Amsterdam UMC, location AMC, once or twice. The questionnaires can be completed either at home or at the outpatient clinic. Completing all questionnaires takes 30 minutes, physical examination including handheld dynamometer takes 1 hour, 6-minute walk test takes 30 minutes, gait analysis takes 2 hours, and muscle strength assessment with Biodex dynamometer takes 2 hours. This is the first study to evaluate body image and objective functional outcome measures after STS resections. This study will give STS patients insight into their body image, quality of life and functioning. This insight may improve their acceptance and create new rehabilitation opportunities (through improved knowledge of individual deficits). The study can only be conducted with these specific patients because STS are rare and only treated in designated *expertise centers* (ERN).

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

To be eligible to participate in this study, a subject must meet all of the following criteria:
- Treated with surgical resection for primary non-metastatic extremity STS at the Amsterdam
UMC between 2010-2021.
- Being able to visit the Amsterdam UMC location AMC once or twice.
- Pregnant patients must agree to be scheduled 5 months after their pregnancy ends.

Exclusion criteria

- Patients who cannot maintain 6 minutes of walking will be excluded from the 6-minute walk test.

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	25-06-2024
Enrollment:	150
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	26-09-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL85908.018.23