The value of a risk prediction tool (PERSARC) for effective treatment decisions of soft tissue sarcomas patients.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24454

Source
Nationaal Trial Register

Brief title
VALUE-PERSARC

Health condition

grade 2-3 soft tissue extremity sarcoma

Sponsors and support

Primary sponsor: KWF kankerbestrijding
Source(s) of monetary or material Support: KWF kankerbestrijding (#12642)

Intervention

Outcome measures

Primary outcome

The co-primary outcomes are decisional conflict (Decisional Conflict Scale(DCS)) and

informed choice. Informed choice is a combined outcome incorporating knowledge, attitudes concerning trade-offs between quality and length of life (QQ_Questionnaire), and treatment decision.

Secondary outcome

Secondary outcomes, include regret (Decision_Regret_Scale) (T3, T4), worry (Cancer_Worry_scale) (T1, T2, T3, T4), involvement in decision-making according to patients (SDM-Q-9) (T1), patient reported outcome using the Patient Reported Outcome Measures (PROMIS Global health) (T1, 2, 3, 4), and (PROMIS physical function) (T1, 2, 3, 4), utilities for the cost-effectiveness analysis (EQ-5D-5L) (T1, T2, T3, T4), health care cost (iMCQ) (T2, T3, T4) and absenteeism/presenteeism from paid work (T2, T3, T4).

Study description

Background summary

Currently, there is no consensus about the optimal treatment for patients with high grade soft tissue sarcomas (STS) which are localized in the extremities. To ensure overall survival, there is a tendency to operate with wide resection margins, but this has a high impact on quality of life especially when limb function must be sacrificed. (Neo)adjuvant radiotherapy allows for narrower surgical margins but is associated with significant short -and long-term side-effects. As evidence on the best treatment is lacking, treatment choice for individual patients should be driven by their weighing of the benefits and harms of the treatment options in light of their personal situation.
However, current treatment decision-making in STS care is one-size fits all, and not informed by individualized risks of treatment options and patients' preferences. Consequently, there is no guarantee that patients with STS will receive treatment that is appropriate for their situation, and patients experience uncertainty about which treatment is best for their personal situation (decisional conflict).
From literature it is known that decision supporting interventions contribute to a better informed choice and less decisional conflict. Therefore, our research group developed a validated personalized risk assessment tool (Personalised Sarcoma Care: PERSARC) which provides patients and STS professionals insight into the personalized risks and benefits of each treatment option based on patient's age, tumor size, tumor depth and histology in their decision-making process.
It is hypothesized that use of PERSARC leads to significantly less decisional conflict in patients and more informed decisions compared to usual care (treatment decisions without use of PERSARC) by reducing the uncertainty regarding risks and benefits of treatment options in high-grade extremity STS patients.

Study objective

It is hypothesized that use of PERSARC leads to significantly less decisional conflict in

patients and more informed decisions compared to usual care (treatment decisions without use of PERSARC) by reducing the uncertainty regarding risks and benefits of treatment options in high-grade extremity STS patients.

Study design

T1 (one week) T2 (3months) T3 (6months) T4 (12months) after treatment decision

Intervention

High-grade extremity STS patients will either receive standard care (control group) or care with the use of PERSARC; i.e. PERSARC will be used in multidisciplinary tumour boards to guide treatment advice and in consultation in which the oncological/orthopaedic surgeon informs the patient about his/her diagnoses and discusses the benefits and harms of all relevant treatment options (intervention group).

Contacts

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Eligibility criteria

Inclusion criteria

Patients (>= 18 years) with primarily diagnosed (histologically confirmed) grade 2-3 extremity STS, who do not have a treatment plan yet and will be treated with curative intent. Patients with sarcoma subtypes or treatment options other than those mentioned in the PERSARC app are unable to participate. Furthermore, patients need to be Dutch fluency and literacy and mentally competent.

Exclusion criteria

• Patient that are treated without curative intent
• Patient that needs to be treated with chemotherapy or isolated limb perfusion
• Patients were surgery is not indicated
• Sarcoma subtypes not mentioned in the PERSARC app

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2021
Enrollment:	231
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-01-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 51872
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9160
CCMO	NL76563.058.21
OMON	NL-OMON51872

Study results