

The value of a risk prediction tool (PERSARC) for effective treatment decision making: a stepped wedge Randomized Controlled Trial.

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To assess whether the use of the personalized risk assessment tool (PERSARC) is (cost)effective in reducing decisional conflict and increasing informed choices in high-grade extremity STS compared to usual care (co-primary outcomes). In addition, we...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Soft tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON51872

Source

ToetsingOnline

Brief title

VALUE-PERSARC

Condition

- Soft tissue therapeutic procedures

Synonym

soft tissue extremity sarcomas

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: KWF kankerbestrijding projectnummer 12642

Intervention

Keyword: informed choice, risk prediction model, sarcomas

Outcome measures

Primary outcome

The co-primary outcomes are decisional conflict (Decisional Conflict Scale(DCS) (T1,) and informed choice (T1). Informed choice is a combined outcome incorporating knowledge, attitudes concerning trade-offs between quality and length of life (QQ_Questionnaire) (T1), and treatment decision (T1).

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

To assess whether the use of the personalized risk assessment tool (PERSARC) is (cost)effective in reducing decisional conflict and increasing informed choices in high-grade extremity STS compared to usual care (co-primary outcomes). In addition, we aim to assess in a process evaluation (a) the extent and way in which PERSARC is used by patients and professionals, (b) how satisfied they were with the use of PERSARC, and (c) whether they experienced barriers and facilitators to the use of PERSARC. These insights in the mechanisms and processes responsible for the success of PERSARC on predefined outcomes will guide future implementation efforts.

Study design

To assess the (cost)effectiveness of PERSARC in treatment decisions of high-grade extremity STS-patients, a parallel cluster randomized trial will be conducted in the 8 Dutch hospitals that are STS expertise centers. Hospitals will be randomized between standard care (control condition) or care with the use of PERSARC (intervention). Outcomes will be assessed within one week after treatment decision has been made (T1), and after 3, 6 and 12 months after the

treatment decision has been made (T2, T3, T4) in at least 120 patients. See main study parameters/endpoints for a description of the outcomes that will be measured at these time points. Actual use of PERSARC, satisfaction with/added value of PERSARC and barriers and facilitators using PERSARC by patients and professionals will be measured in a process evaluation using questionnaires, interviews, and audio-recording/observation of consultations and multidisciplinary meetings.

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).

Study burden and risks

The risk of this study are comparable with the risk of standard care. However for patients allocated to the intervention group, it can be difficult to hear about ones prognosis and to be actively involved in his/her own treatment decision. Both groups (intervention and control) are asked to fill out questionnaires within one week after the treatment decision has been made, and 3, 6 and 12 months after treatment decision has been made. Each questionnaire can be filled in online and will take approximately 30 minutes. In total study participants spend 130 minutes on this study (including informed consent consultation (+/- 10min).

Furthermore, 5-15 randomly selected patients will be asked for an interview about their experiences of their decision-making process with their orthopaedic surgeon/ oncologist. These interviews will take about 45 minutes.

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

- Patients ≥ 18 years
- Histologically diagnosed with grade 2-3 STS in their extremities.
- Who do not have a treatment plan yet
- Dutch fluency and literacy
- Mentally competent
- Signed informed consent
- Patient owns smartphone with internet access (WiFi)

Exclusion criteria

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

In summary: patients with sarcoma subtypes and/or patients that need to be treated with other treatment modalities than those mentioned in the PERSARC app are excluded.

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	24-08-2021
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	a risk prection tool (PERSARC) in a mobile app
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	19-05-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	10-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 10-06-2022
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24454
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL76563.058.21
Other	NL9160
OMON	NL-OMON24454