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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24454

Bron
Nationaal Trial Register

Verkorte titel
VALUE-PERSARC

Aandoening

grade 2-3 soft tissue extremity sarcoma

Ondersteuning

Primaire sponsor: KWF kankerbestrijding
Overige ondersteuning: KWF kankerbestrijding (#12642)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2021
Aantal proefpersonen:	231
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-01-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 51872
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten