Health-related quality of life in patients with advanced soft tissue sarcomas treated with chemotherapy: The HOLISTIC study

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Background: Around half of patients with intermediate or high-grade soft tissue sarcomas (STS) will develop advanced disease. The mainstay of treatment for advanced STS is chemotherapy. Although treatment intent is usually palliative, the degree to which chemotherapy affects symptoms of disease, patient functioning and health-related quality of life (HRQoL) is rarely measured nor incorporated into clinical trials. Radiological response rates, time to progression and survival are traditionally used to measure treatment benefit. Therapeutic decisions are often challenging due to modest response rates and treatment-related adverse events. HRQoL is perceived by some patients as of equal- or greater importance than survival. Clinicians should be able to provide HRQoL data to patients to enhance the shared decision-making process and encourage a holistic approach to care. The aim of this study is to assess HRQoL in patients with advanced STS treated with 1st line chemotherapy, explore the decision-making process and evaluate patient post-treatment reflection.

Trial design: This is a longitudinal cohort study for patients aged \( \geq 18 \) years with advanced STS (n = 132) who are treated with 1st line chemotherapy. Patients from 8 centres (United Kingdom 3, The Netherlands 5) are invited to complete questionnaires at baseline, each cycle of chemotherapy and three-monthly during follow-up. Data collection will be done within PROFILE, an established international registry for cancer patient reported outcomes. Questionnaires include patient demographics, decisional conflict scale, control preferences scale, quality-quantity questionnaire, treatment expectations, EORTC-QLQ-C30, FACT-G (2 items), work-ability index, financial toxicity and decisional regret scale. Clinical details, such as STS histology, will be collected from patient records and linked to questionnaire data. The primary endpoint is change in global HRQoL from baseline to Cycle 4 of chemotherapy. Exploratory endpoints include HRQoL functioning scales and symptoms. Recruitment started February 2018; 57 patients have completed (at least) the baseline questionnaire. (May 2019).

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