Title: Results of the interim analysis of the Dutch GRAFITI study.

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Abstract

Aggressive fibromatosis is notorious for its unpredictable clinical course and high recurrence rates after surgical treatment. Nowadays there is a trend towards a more conservative approach for asymptomatic patients. The GRAFITI study is a Dutch prospective registration trial on growth behavior of aggressive fibromatosis without therapeutic intervention. Patients diagnosed with extra-abdominal or abdominal wall aggressive fibromatosis who did not receive previous treatment for the present tumor are included in this study. The primary aim is to assess the outcome of the watchful waiting approach as an initial treatment choice by scheduled follow-up with ultrasound and MRI imaging. Secondary outcomes are quality of life during this watchful waiting policy, measured with EORTC qLq-c30 questionnaires. The interim analysis is conducted after the inclusion of the first 20 patients, with a minimal follow up of 1 year. The cut off for premature termination was set on 50% of patients discontinuing watchful waiting strategy. Of the first 20 patients included in this study, 15 patients (75%) have continued the watchful wait policy, while 5 patients (25%) continued with active treatment including operative treatment (n=3) and radiotherapy (n=2). This interim analysis indicates that we can continue the GRAFITI study and that a conservative approach seems to be an acceptable treatment strategy for patients diagnosed with extra-abdominal and abdominal wall aggressive fibromatosis.