Study on growth behavior of desmoid tumors with monitoring.

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Wait and see policy is a suitable approach for selected patients with aggressive fibromatosis.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27891

Bron
NTR

Verkorte titel
GRAFITI

Aandoening

Aggressive fibromatosis
Desmoid tumors

Ondersteuning

Primaire sponsor: Erasmus MC Cancer Institute
Overige ondersteuning: initiator/sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess tumor progression in terms of objectifying and monitoring growth during watchful waiting policy as an initial treatment for extra-abdominal and abdominal wall aggressive fibromatosis.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The efficiency of surgery and radiotherapy in the treatment of aggressive fibromatosis is disputed and there is a shift towards a more conservative approach. The aim of this study is to adhere to a “watchful waiting’” policy in patients with aggressive fibromatosis objectifying and monitoring tumour growth.

Objective: The primary objective is to assess the outcome of a watchful waiting approach as an initial treatment for extra-abdominal and abdominal wall aggressive fibromatosis. The secondary objective is to investigate quality of life during a watchful waiting policy. Other objectives are the identification of factors associated with tumour growth, in particular the relation with the presence of a CTNNB1-gene mutation in the tumour.
Study design: Prospective observational study.
Study population: Patients diagnosed with extra-abdominal or abdominal wall aggressive fibromatosis who did not undergo previous treatment for the present tumour.

Intervention: In all patients a watchful waiting-policy is adhered to and imaging studies will be performed during the follow-up period according to a protocol.

Main study parameters/endpoints: The main study parameter is the occurrence of tumour progression, defined according to the RECIST criteria as an increase of at least 20% of the sum of the longest diameter in comparison to the smallest sum of the longest diameter recorded since (or at the time of) inclusion.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participation in the study implies that the work-up of the tumour does not deviate from usual work-up. It consists of a medical history, physical examination, ultrasound-guided biopsy and an MRI-scan. The ultrasound and MRI-scan containing tumour measurements will serve as a reference for further ultrasounds and scans. In addition, a questionnaire is completed by the patient. The follow-up schedule is set for 9 outpatient-clinic visits. During each visit, a medical history, physical examination and imaging studies will be performed in order to monitor possible growth. The follow-up schedule in the presented study is slightly different from the national sarcoma follow-up protocol, in order to monitor patients more closely during the first year. In addition, patients will be asked to complete a questionnaire during 5 follow-up visits. We consider this burden to be low. The tumour will progress in a number of patients as the progression rate is the endpoint of the study. In order to minimize the risk of compromised abilities due to tumour growth, the follow-up schedule allows for timely detection of tumour progression on the one hand and patients with vital structures at risk will not be included in the study. The exclusion criteria prevent life threat or functional impairment in case of tumour growth. This study will provide insight in tumour behavior and clinicopathological factors predictive of tumour progression.

Doel van het onderzoek

Wait and see policy is a suitable approach for selected patients with aggressive fibromatosis.

Onderzoeksopzet

Interim analysis after 1 year follow-up for 20 patients.

Onderzoeksproduct en/of interventie

watchful waiting policy

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Histological evidence of aggressive fibromatosis.

- Capable of undergoing MRI-scans and ultrasound.

- Nu functional impairment due to the tumor.

- Capable of understanding and signing informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients under 18 years of age.

- Personal of family history of FAP.

- Intra-abdominal tumor localization.

- Potential life treat or imminent functional impairment in case of tumor progression.

- Unavoidable mutilation in case of tumor progression.

- Severe pain associated with the tumor.

- Patients who have undergoing local or systemic treatment for the present manifestation of aggressive fibromatosis.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2014
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-08-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4489
NTR-old	NTR4714
Ander register	METC : MEC-2014-124

Resultaten