Towards a minimally invasive approach of atypical lipomatous tumors: the MINIMALIST trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27031

Source
Nationaal Trial Register

Brief title
MINIMALIST

Health condition

- Atypical lipomatous tumor
- Well-differentiatied liposarcoma
- Lipoma

Sponsors and support

Primary sponsor: Erasmus MC Cancer Institute
Source(s) of monetary or material Support: Initiator/sponsor

Intervention

Outcome measures

Primary outcome

The main study endpoint is the choice of treatment (i.e. AS or surgery) to determine the

feasibility of AS and the occurrence of dedifferentiation to determine the safety. Dedifferentiation has to be pathologically proven upon biopsy or resection.

Secondary outcome

- Tumor growth/progression: To evaluate progression/tumor growth, the diameter of the tumor will be measured in three dimensions. Progression is defined as having twice progressive disease on two consecutive MRI-scans. Progressive disease (PD) is defined as an increase of ≥20% in the sum of diameters compared to the sum of diameters of the prior MRI documented during the study period, in accordance with the Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1).
- Motives for treatment decision making and switching: Patients will be asked why they have chosen one of the two treatment modalities, or why they want to switch from active surveillance to surgery (if applicable).
- Validation of the radiomics model: For the evaluation of the radiomics model, we will use the area under the ROC curve (AUC), accuracy, sensitivity, specificity, negative predictive value and positive predictive value.
- Health-related Quality of Life: To evaluate the prevalence and changes in HRQoL a baseline questionnaire and 5 different HRQoL questionnaires will be used: the General Self Efficacy (GSE) questionnaire (Dutch version 1994), the EORTC-QLQ C30 (version 3), the HADS (Dutch version 1997) the TESS (Dutch version 2017) and the Decision Regret Scale (Dutch version 2010).
- Biobank: Biobank consisting of biopsies and (if applicable) resection specimens for future translational research.

Study description

Background summary

Rationale: Patients with an atypical lipomatous tumor (ALT) have an excellent prognosis, approaching 100% survival after 10 years of follow-up. Currently, we might be 'overtreating' these patients with surgery and radiotherapy, thereby inducing morbidity and even mortality. Despite this excellent prognosis, active surveillance is barely applied in these patients. Furthermore, survival might not be the only appropriate outcome to measure, and other outcomes, such as health-related quality of life (HRQoL), might have become more relevant. Second, it can be very difficult to distinguish between ALTs and lipomas based on imaging. Therefore, these patients currently need a painful and invasive biopsy for pathological examination to make the distinction. Finally, due to the rarity and heterogeneity of liposarcomas, it is a challenge to collect a large homogeneous set of tissue samples for translational research.

Objective: The aim is to develop a minimally invasive approach of both diagnosing and treating ALTs, saving these patients a biopsy, surgery-related complications and morbidities amongst others. As a first step towards a minimally invasive diagnosis, a radiomics model

was developed on a retrospective cohort to distinguish lipomas from ALTs based on MRI scans. In the current study, one of the objectives is to prospectively validate this radiomics model. Second, to prevent the 'overtreatment' of ALT patients, the aim is to explore the feasibility and safety of active surveillance (AS) as a treatment option for ALTs, including evaluating the HRQoL. Lastly, the objective is to build a biobank of the biopsies and, if applicable, resection specimens obtained during the study for future translational research.

Study design: Prospective single center observational cohort study

Study population: Patients with a lipomatous tumor suspected for ALT or lipoma, aged ≥18 years, who did not receive any treatment for their tumor yet.

Intervention (if applicable): All patients will undergo an MRI scan and a biopsy, as part of the routine diagnostic work-up. If proven ALT, patients may choose either surgery (standard care) or AS ('intervention'). Follow-up for patients choosing AS, will be performed according the study protocol, including regular imaging.

Main study parameters/endpoints: The main study endpoints are choice of treatment (i.e. AS or surgery) to determine the feasibility of AS and the occurrence of dedifferentiation to determine the safety of AS. AS will be considered feasible if at least 25% of the patients prefers AS over surgery, of whom at least 50% is still being treated with AS after one year of follow-up. AS will be considered safe if dedifferentiation occurs in <5% of the patients. Dedifferentiation has to be pathologically proven upon biopsy or resection. Second, to validate the accuracy of the radiomics model, the area under the ROC curve (AUC), accuracy, sensitivity, specificity, negative predictive value and positive predictive value will be used. To evaluate the prevalence and changes in HRQoL we will use different HRQoL questionnaires.

Study objective

Active surveillance is a reasonable treatment option for selected ALT patients

Study design

Interim analysis after 1 year follow-up for 50 patients

Intervention

Active surveillance

Contacts

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Eligibility criteria

Inclusion criteria

- Aged ≥18 years
- Primary or recurrent lipomatous tumor suspected for lipoma or atypical lipomatous tumor
- Adequate understanding of the Dutch or English language (to fill out the HRQoL questionnaires)

Exclusion criteria

- Tumor localization in the mediastinum, retroperitoneum or testis/scrotum
- Diagnosis through excisional biopsy
- Any type of treatment for the current tumor (i.e. in case of recurrence, treatment of the prior tumor(s) is allowed)
- Signs/suspicion of dedifferentiation in the biopsy specimen at time of diagnosis
- Unable to undergo regular MRI-scans (for example because of a pacemaker, claustrophobia)
- Systemic treatment for any other concurrent malignancy
- Currently receiving radiotherapy at affected site for other concurrent disease
- Incapable to understand the study, to sign informed consent or to fill out the HRQoL-questionnaires

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-06-2020
Enrollment:	238
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	24-06-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8738
Other	METC EMC : MEC-2020-0175

Study results