Development of a platform of Patient Derived Xenografts (PDX) and 2D/3D cell cultures of Soft Tissue Sarcomas (STS): Protocol to obtain tumour material from patients with (non)-metastatic sarcomas.

Published: 25-11-2016 Last updated: 30-01-2025

To collect a platform of 2D/3D cell cultures (organoids) of Soft Tissue Sarcomas.To collect a platform of Patient Derived Xenografts (PDX) of Soft Tissue Sarcomas of patients with (non-) metastatic sarcomas.To study the take rate of fresh PDX tumour...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue neoplasms
Study type	Observational invasive

Summary

ID

NL-OMON47127

Source ToetsingOnline

Brief title Sarcoma PDX

Condition

- Musculoskeletal and connective tissue neoplasms
- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym

soft tissue sarcoma

Research involving

Human

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Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis **Source(s) of monetary or material Support:** de EORTC-STBSG en de stichting HDKT

Intervention

Keyword: 2D/3D cell cultures, PDX, response evaluation, Sarcoma

Outcome measures

Primary outcome

To collect a platform of Patient Derived Xenografts (PDX) and 2D/3D cell

cultures of Soft Tissue Sarcomas.

Secondary outcome

not applicable

Study description

Background summary

Soft tissue sarcomas are rare and knowledge on the individual radiation sensitivity is lacking. Performing prospective clinical studies into different types of therapy in humans is hampered by the rarity of the disease.

Study objective

To collect a platform of 2D/3D cell cultures (organoids) of Soft Tissue Sarcomas.

To collect a platform of Patient Derived Xenografts (PDX) of Soft Tissue Sarcomas of patients with (non-) metastatic sarcomas.

To study the take rate of fresh PDX tumour material in nude mice.

To produce a consistent system for further anti-sarcoma therapy (both RT and chemotherapy experiments)

To produce a model for translational research, for example systemic therapy sensitivity assays.

To study the passage possibilities of 2D/3D cell cultures (organoids) by freezing, storing and thawing.

To study the passage possibilities of PDX tumour material by freezing, storing, thawing and re-inoculating in nude mice.

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To study fractionation sensitivity on several STS subtypes in PDX.

Study design

the collection of fresh tumor material

Study burden and risks

one blood draw and, if necessary, one single extra tumor biopsy (4 needle biopsies) under local anesthesia

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

- Histologically confirmed (non-)metastatic intermediate to high grade STS
- Local recurrences are allowed
- Age >= 18 years
- Able and willing to undergo tumor biopsies or tumour sampling during surgery
- Localization of sarcoma enables safe biopsy or surgery
- Written informed consent

Exclusion criteria

Known coagulation disorder and/or anticoagulant medication in as far it might interfere with a safe biopsy procedure (to the discretion of the treating physician and attending radiologist).
Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the study.

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Treatment	

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	06-09-2017
Enrollment:	40
Туре:	Actual

Ethics review

Approved WMO

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Date:	25-11-2016	
Application type:	First submission	
Review commission:	METC NedMec	
Approved WMO Date:	12-10-2017	
Application type:	Amendment	
Review commission:	METC NedMec	
Approved WMO Date:	16-02-2018	
Application type:	Amendment	
Review commission:	METC NedMec	
Approved WMO Date:	11-06-2020	
Application type:	Amendment	
Review commission:	METC NedMec	

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 ClinicalTrials.gov CCMO ID NCT02910895 NL58626.031.16