Biobanking for characterization of pediatric malignancies.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	-

Summary

ID

NL-OMON21619

Source
Nationaal Trial Register

Brief title
PMC Biobank

Health condition

All patients suspected of, diagnosed with and/or treated for, or in follow-up for a pediatric malignancy at the Princess Maxima Center for pediatric oncology.

Sponsors and support

Primary sponsor: Prinses Maxima Centrum voor kinderoncologie
Source(s) of monetary or material Support: Prinses Maxima Centrum voor kinderoncologie

Intervention

Outcome measures

Primary outcome

Establish a biobank of patient material for future biomedical research. As such there is no formal endpoint or statistical consideration regarding the size of the biobank.

Secondary outcome

None

Study description

Background summary

Rationale: Significant progress has been made in the cure of pediatric cancer through treatment optimization and improvement of supportive care. Despite major advances, 25% of children with cancer currently die due to lack of effective treatment. Furthermore, many patients suffer from a large diversity of side effects. By setting up a biobank, consisting of different kinds of patient samples from tumor and healthy tissues, future research will be made possible, which will be the focus of specific research projects. To enable this future research all samples will undergo extensive baseline characterization including the generation of standardized tumor models, in the form of tumor organoids and patient-derived mice xenografts (PDX mice). By enabling extensive characterization, the biobank will help to address specific research question and may therefore contribute to the development of improved treatment regimes in the future in several ways (Figure 1).

A Biobank: tumor, blood, DNA, RNA, cerebrospinal fluid, ascites, pleural effusion, feces, urine, saliva etc

B Baseline characterization through: Genomic analyses
DNAseq RNAseq methylDNA microbiome

& Tumor models
Organoids POX mice

C Improved characterization of tumors for future research

Figure 1: Overview. A) Biobank. B) Characterization of tumors directly and indirectly (through tumor models). C) Future research enabled through the biobank.

Furthermore, centralized care in the Princess Maxima Centre (PMC) will provide the opportunity to collect not only relevant baseline data, but also to launch a prospective longitudinal cohort data warehouse of treatment, early and late side effects and its determinants, of all children with cancer already in the diagnostic and treatment phase and follow-up post-treatment, thereby building the basis for several ambitious research lines. These data are necessary for interpretation of biologic characterization.

Goal: The aim is to set up a biobank consisting of prospectively collected material (described in detail in the biobank manual), from all patients diagnosed with a malignant disease and treated at the Princess Maxima Center for Pediatric Oncology (Figure 1A).

The extensive baseline characterization of tumors and healthy tissues will comprise a variety of genomics approaches such as for example whole genome sequencing, RNA sequencing,DNA methylation and microbiome analyses, as well as indirectly through the generation of tumor models using organoid technology and POX mice (Figure 1B).
The resulting resources (primary samples, tumor models, clinical data) will enable future research aimed at improving treatment. For example, the availability of tumor models as a "living biobank" may aid the development and testing of new drugs, and the availability of genomics data may improve patient stratification for new and emerging therapies. Such questions will however be addressed in specific future research protocols that may make use of the resources of the PMC biobank. When required, such projects will undergo ethics committee approval prior to being initiated.

Study design: Additional material from primary diagnostics will be stored according to good clinical/laboratory practice (GCP and GLP). The stored material will vary from tumor (biopsies), DNA, bone marrow, cerebrospinal fluid and other body fluids, to peripheral blood, stools, saliva, and urine. Most tissues will be obtained when the patient is undergoing procedures as as standard of care. In all cases we will do the utmost to minimize risk and burden for the patient and try to minimize harm.

Clinical data, as collected at diagnosis, during follow-up and at the end of treatment will be available. In addition, the baseline information on direct and late toxicity will be documented at certain timepoints during treatment and at follow-up. Clinical data and material can only be requested via the Biobank Committee, as described in 8.3.

Study population: All patients who are suspected of, diagnosed with and/or treated for, or in follow-up for, a pediatric malignancy at the Princess Maxima Center for Pediatric Oncology.

Main study endpoint: Establishment of a biobank with material from patients with a pediatric malignancy.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participation may involve some additional risk/burden, such as bruises when additional blood sampling is performed, or bleeding when additional biopsy material is required. These risks will always be carefully considered. Furthermore, biobank procedures will only be performed in conjunction to standard of care to mitigate such risks.
As further research may include molecular profiling of the tumor, germline material will be analyzed in order to compare with tumor profile. Although it is not the main purpose of those studies, germline aberrations can be detected. Depending upon the informed consent, patient and/or parents have declared whether they want to be informed. Patient /parents will be referred to a clinical geneticist for confirmation and counseling. With regard to group relatedness: since this biobank is aimed as a resource for future projects which focus on improvement of the outcome of pediatric cancer, we cannot use tissues from adult patients or other material.

Study objective

Not applicable

Study design

See protocol

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

- Diagnosis and/or treatment in the Princess Maxima Center.
- Written informed consent according to (inter)national law and regulations

Exclusion criteria

- Patients for whom the physicians or investigators considers that participation in this study is either not appropriate or poses unacceptable risks for the patient (e.g. when collection of additional material poses too many risks or potential harm).

Study design

Design

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-01-2017
Enrollment:	2750
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
Not applicable

Ethics review

Not applicable

Application type:	Not applicable

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	NL7744
Other	METC Rotterdam : MEC-2016-739 (Niet-WMO plichtig)

Study results

Summary results
Not applicable