New strategies to detect cancers in carriers of mutations in RB1: blood tests based on tumor-educated platelets, or extracellular vesicles.

No registrations found.

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

Summary

ID

NL-OMON28055

Source
Nationaal Trial Register

Brief title
NIRBTEST

Health condition

Retinoblastoma

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: This project is financially suported by TRANSCAN

Intervention

Outcome measures

Primary outcome

1. Determine the non-cancerous baseline in adult RB1-mutation carriers (Rb-survivors).
2. Contribute to the biobanking of blood and cancerous tissues from RB1-mutation carriers with SPMs.

Secondary outcome

None

Study description

Background summary

Rationale: Individuals with a cancer predisposition due to a mutation in the paradigm tumor suppressor gene RB1, have a high risk to develop the childhood cancer retinoblastoma (Rb). Biopsies are not possible in Rb, before treatment selection. Heritable Rb patients have also a high risk to develop other types of second primary, either childhood or adult, malignancies (SPMs), notably sarcomas and melanomas. Remarkably, SPMs are now the leading cause of death in heritable-Rb-survivors. Unfortunately, there are no well-developed regular surveillance protocols for SPMs in Rb survivors available right now. Recently, new non-invasive cancer test have been developed, based on either RNA-sequencing data from platelets (ThromboSeq), or on extracellular membrane vesicles (EVs) derived from tumor cells present in blood.
Objective:
- Determine the non-cancerous baseline in adult RB1-mutation carriers (heritable-Rb-survivors).
- Contribute to the biobanking of blood and cancerous tissues from RB1-mutation carriers with SPMs.
- The development of blood-based tests, either platelet or EV-based, for the detection of (the type of) tumors in RB1-mutation carriers.
Study design: Cross-sectional multicenter trial.
Study population:
- 40 Rb patients (children),
- 40 controls (children),
- 153 Rb survivors (adults),
- 153 controls (adults),
- 10 Rb survivors with SPM (children/adults).
Main study parameters/endpoints:
- Determine the non-cancerous baseline in adult RB1-mutation carriers (heritable-Rb-survivors).
- Contribute to the biobanking of blood and cancerous tissues from RB1-mutation carriers with SPMs.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Two blood samples totalling 10ml blood will be collected for every participant. Additionally, a

short questionnaire has to be filled in concerning their and their family’s cancer history. Blood draws will be done, when participants are already present in the hospital for other appointments, and thus no extra visits are required. For all children, blood will be collected through an already present IV, and so no extra venepuncture is required. Children have to be included because Rb is a tumor only present in this patient group.

Study objective

Possibly the baseline in Rb survivors and Rb children is different from control patients.

Study design

1 timepoint and in case of developped SPM a second timepoint

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

criteria:
- Adult:
o Group 1: germline mutation RB1.
o Group 2 (control): no germline mutation RB1.
- Pediatric:
o Group 1: somatic or germline mutation RB1

o Group 2 (control): no mutation RB1.

Exclusion criteria

- Adult:
o Group 1: concomitant heritable (inherited) disorder other than caused by monoalleic mutation of RB1.
o Group 2 (control): cancer or already known cancer predisposition syndrome.
- Pediatric:
o Group 1: concomitant heritable (inherited) disorder other than caused by monoalleic mutation of RB1.
o Group 2: cancer or already known cancer predisposition syndrome.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-12-2018
Enrollment:	396
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	10-09-2019
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	NL8013
Other	METC VUMC : METC2018.095

Study results