# Cognitive Functioning And Health Related Quality Of Life In Retinoblastoma Survivors: The Role Of Cancer Treatment And Repeated Anesthesia

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The specific aim of the current study is to investigate the impact of oncological treatment and multiple GA in Rb survivors and Rb risk carriers (8-35 years) on cognitive functioning, psychosocial functioning and HRQoL. Furthermore, psychological…

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON53703

**Source**
ToetsingOnline

**Brief title**
RbNeuroQoL study

### Condition

- Other condition
- Ocular neoplasms
- Cognitive and attention disorders and disturbances

**Synonym**
Eye cancer, retinoblastoma

**Health condition**

gezondheidsgerelateerde kwaliteit van leven

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Amsterdam UMC
**Source(s) of monetary or material Support:** SKOCA;UitZicht;CCA;nalatenschap van een patiënt

## Intervention

**Keyword:** Cognition, HRQoL, Psychosocial, Retinoblastoma

## Outcome measures

### Primary outcome

1. To assess cognitive functioning (C1), psychosocial functioning (C2 ) and

HRQoL (C3) in Rb survivors and Rb risk carriers

2. To investigate the effects of biological and physiological factors on

cognitive functioning, psychosocial functioning and HRQoL in Rb survivors and

Rb risk carriers.

3. To assess psychosocial functioning (C2) and HRQoL (C3) in parents (child

0-12 years old).

4. To study associations between outcomes (C0, C1, C2 and C3) in Rb survivors

and Rb risk carriers, and their parents.

### Secondary outcome

1. To map neuropsychological profiles in Rb survivors and Rb risk carriers

(8-35 years)(within C1).

2. To map symptoms of psychosocial functioning in Rb survivors, Rb risk

carriers (8-35 years and parents)(within C2).

# Study description

### Background summary

Retinoblastoma (Rb) is the most common form of ocular cancer in children, with high survival rates in developed countries (>90%). Rb can develop unilateral (sometimes hereditary), or bilateral (always hereditary). Children are usually diagnosed at a young age (< 5 years) and are subjected to an intensive treatment and follow-up protocol immediately after. If Rb is diagnosed in early disease stages, eye-saving treatment could be provided, such as laser, cryo-, chemotherapy and/or radiotherapy -or a combination of these. When discovered in a later disease stage, enucleation is often inevitable. Brothers and sisters or offspring of heredity Rb survivors that are at risk to develop Rb themselves (so called *Rb risk carriers*) will be screened according to the Dutch Rb Screening Protocol. The medical treatment and follow-up of Rb patients and screening of Rb risk carriers takes place under general anesthesia (GA) up to four or five years of age. At this age the brain is still developing and therefore extra vulnerable to iatrogenic damage, including neuropsychological complications. Immediate effects of the oncological treatment, as well as secondary effects due to multiple GA on cognitive development in Rb survivors is still understudied. Rb survivors report disease-related limitations in daily life and lower health related quality of life (HRQoL), which might be related to impaired cognitive functioning. Apart from possible immediate or secondary treatment effects, children with Rb are known to be experiencing psychosocial struggles, including anxiety and depression, declined participation and/or pediatric trauma, which may negatively affect HRQoL as well. Despite the impact on general wellbeing and HRQoL, the cognitive and emotional aspects of Rb are largely under addressed in pediatric care. It is important to gain insight in the cognitive development and psychosocial functioning from childhood into young adulthood of Rb survivors, as well psychosocial functioning of the parents in order to provide timely interventions, minimizing possible long-term consequences. It is hypothesized that extensive treatment and multiple GA is negatively associated with cognitive functioning, psychosocial functioning and HRQoL in Rb survivors and Rb risk carriers. Moreover, that psychological struggles and/or trauma strengthen these associations.

### Study objective

The specific aim of the current study is to investigate the impact of oncological treatment and multiple GA in Rb survivors and Rb risk carriers (8-35 years) on cognitive functioning, psychosocial functioning and HRQoL. Furthermore, psychological struggles of parents in terms of anxiety, depression, parental distress and parental trauma of parents of young Rb patients/survivors, and risk carriers (0-12 years), will be also taken into

account.

### Study design

A cross-sectional observational cohort study will be conducted with three core outcomes:
1. Cognitive functioning of Rb survivors and former Rb risk carriers (8-35 years old); using comprehensive and neuropsychological testing addressing estimated intelligence, tempo and processing speed, memory, language, visual motor integration, attention and executive functioning.
2. Psychosocial functioning of Rb survivors and former Rb risk carriers (8-35 years old); using online questionnaires addressing anxiety, depression, adaptive functioning and activity and pediatric trauma.
3. Psychosocial functioning of parents (child 0-12 years old); using online questionnaires addressing anxiety, depression, parental distress and parental trauma.

Nationwide norm data will be used for both neuropsychological- as well as questionnaire outcomes to assess clinical significance. Outcomes of Rb patients/survivors and (former) Rb risk carriers will be compared to each other as well.
Within the Rb survivors cohort different treatment groups will be discerned and compared to each other: such as only enucleation (EN), versus only focal therapy (FT), versus only selective intra-arterial chemotherapy (SIAC), versus only radiotherapy (RT), versus combinations of those treatments, including systemic chemotherapy.

### Study burden and risks

The neuropsychological assessment regards one appointment and will be assessed in combination with a regular out-patient visit to the ophthalmology department, or at the survivors* or Rb risk carrier*s own home. Digital questionnaires are completed at the participants home in their own time on their personal computer. Physical or psychological discomfort is expected to be low to moderate and aftercare is provided when necessary. Presentation of retinoblastoma only occurs during childhood and therefore it is important to now the (late) effects of treatment and follow-up on development during childhood and adolescence. Furthermore, problems regarding cognitive functioning, psychological functioning and HRQoL can differ with age.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

## Inclusion criteria

Cognitive functioning, psychosocial functioning and HRQoL in Rb survivors and former Rb risk carriers (neuropsychological assessment and questionnaires):
In order to be eligible for inclusion the potential participant must meet all inclusion criteria:
1. Rb diagnosis, (main)treatment and follow-up of Rb patients and -survivors, or Rb screening took place at the Dutch Retinoblastoma Expertise Center of the Amsterdam University Medical Centers,
2. Rb survivor or former Rb risk carriers is between 8 and 35 years old,
3. Average understanding of the Dutch language.

Psychosocial wellbeing of the caregiver and pediatric trauma (only questionnaires):
In order to be eligible for inclusion the potential participant must meet all inclusion criteria:
1. Being a caregiver of a Rb survivor or Rb risk carrier that have been diagnosed and receive(d) (main) treatment and follow-up or screening at the

Dutch Retinoblastoma Expertise Center of the Amsterdam University Medical Centers,
2. The related Rb survivor or Rb risk carrier is < 12 years old,
3. Average understanding of the Dutch language.

### Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:
1. Pre-existing documented developmental delay and/or severe cognitive impairments (IQ <70),
2. Having an active, uncontrolled psychiatric illness,
3. Rb diagnostic trajectory, treatment and follow-up at another hospital or before the founding of the Dutch Retinoblastoom Expertise Center in 1991. With exception of Rb survivors (diagnosed >1991) who apart from treatment at the Dutch Retinoblastoma Center also required specialized treatment (such as radiation) at another center: they are illegible for inclusion.

## Study design

### Design

**Study type:** Observational non invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Prevention |

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 26-10-2023 |
| Enrollment: | 660 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 01-03-2023 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 22-04-2025 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

# 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 |
|---|---|
| CCMO | NL82126.029.22 |