# Rolandic Care Program

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The overall aim of this study is to identify developmental deficits in children with Rolandic epilepsy. If developmental deficits are observed, we hope to determine timing, persistence, and prognostic factors for developmental deficits and improve...

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|---|---|
| **Ethical review** | Not approved |
| **Status** | Will not start |
| **Health condition type** | Seizures (incl subtypes) |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON45331

**Source**
ToetsingOnline

**Brief title**
n.a.

### Condition

- Seizures (incl subtypes)
- Developmental disorders NEC
- Age related factors

**Synonym**
epilepsy; seizures

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Epilepsiecentrum Kempenhaeghe
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** EEG, natural course, Neuroccognitive and behavioural development, Rolandic epilepsy

## Outcome measures

### Primary outcome

Identification of prognostic variables regarding seizure frequency, EEG and

neuropsychological investigations.

### Secondary outcome

n.a.

# Study description

### Background summary

Rolandic epilepsy, or benign childhood epilepsy with centrotemporal spikes (BCECTS), is the most prevalent type of paediatric epilepsy. Recent studies suggest that prognosis of Rolandic epilepsy might not be as benign as its name suggests. Overall cognition scores are generally within reference ranges, but several aspects of cognition seem to be negatively affected by Rolandic epilepsy: language, visuomotor coordination, memory, and attention span.

Most of our knowledge on Rolandic epilepsy and interrelated factors are derived from cross-sectional cohort studies and post-hoc analyses of age effects, whereas only a few studies investigate the Rolandic epilepsy longitudinally (Lindgren, 2004, Ay 2004). Understanding development of these children and being able to identify children prone to developmental deterioration is crucial in order to offer proper guidance in a clinical setting. This longitudinal study aims to analyse developmental deficits in children suffering from Rolandic epilepsy by investigating clinical, cognitive, behavioural, and academic functioning.

### Study objective

The overall aim of this study is to identify developmental deficits in children

with Rolandic epilepsy. If developmental deficits are observed, we hope to determine timing, persistence, and prognostic factors for developmental deficits and improve early identification and counseling of children at risk.

### Study design

This is an observational study in children with proven Rolandic epilepsy who visit the outpatient clinic of Kempenhaeghe within the program "Child, school and epilepsy". This program includes standard visits with 24-hours-EEG recordings, neuropsychological evaluation and questionaires for both teachers and parents.
Children will be investigated at baseline and after 1 and 2 years. A small amount of children will be asked at age 15 (after puberty and when Rolandic epilepsy will no longer be present) for follow-up investigation, including 24-hours-EEG recordings and neuropsychological investigation.

### Study burden and risks

While children in this study will have litlle benefit of enrollment. they do however benefit from the extensive diagnostic investigations. For example, results of neuropsychological tests can be used for changing the mentoring system at school. For parents there is counseling and it may help in the reduction of prescribing anti-epileptic drugs.
Scientific results derived from this study may be of influence in future treatment and follow-up.

Taking part in this study is a time-effort. The 24-hour EEG-system is carried by the child for 24 hours (electrodes and battery in a small backpack). During this time the child is not able to bathe or shower. Most children are familiar with this type of investigation during the diagnostic procedure regarding the epilepsy.
In the neuropsychological investigations the child sits together with the investigator in a testing room. This can be both intensive and fun because most tests are computer based and many children are used to do that in their spare time.

## 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)
Elderly (65 years and older)

## Inclusion criteria

Rolandic epilepsy (clinical and electrophysiological criteria)
children aged between 4-16

## Exclusion criteria

Seizures that are not classified as Rolandic seizures (clinical and electrophysiological grounds)
Parents or participants (aged 12 or older) that are not willing to provide informed consent

# Study design

### Design

**Study type:** Observational non invasive

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 125 |
| Type: | Anticipated |

## Ethics review

Not approved

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|---|---|
| Date: | 09-04-2018 |
| Application type: | First submission |
| Review commission: | METC Maxima Medisch Centrum (Veldhoven) |

## 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 | NL60546.015.17 |