

# Cognition in patients with Juvenile Myoclonus Epilepsy and their first degree healthy family members

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Key Question: What is the level of cognitive performance in healthy siblings of juvenile myoclonic epilepsy patients compared to that of patients with juvenile myoclonic epilepsy?

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Seizures (incl subtypes)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON42709

### Source

ToetsingOnline

### Brief title

Cognition in JME family members

### Condition

- Seizures (incl subtypes)

### Synonym

Epilepsy, Seizures

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Stichting Epilepsie Instellingen Nederland

**Source(s) of monetary or material Support:** geen

## Intervention

**Keyword:** Cognition, family members, JME (Juvenile Myoclonic Epilepsy)

## Outcome measures

### Primary outcome

raw scores on the neuropsychological tests.

### Secondary outcome

geen

## Study description

### Background summary

There is much insight in cognition in patients with a symptomatic epilepsy, but there is little insight in cognition in patients with idiopathic generalized epilepsy (IGE).

Juvenile myoclonic epilepsy (JME) is the most common idiopathic generalized epilepsy. There is evidence in the literature that JME patients have more cognitive deficits in comparison with healthy individuals. Genetics may play a role in the development of JME, which may imply that the cognitive functioning of relatives of JME patients are also affected. However there is little research. The purpose of this study is to gain more insight into the cognition of patients with JME and cognition in healthy siblings of patients with JME.

### Study objective

Key Question: What is the level of cognitive performance in healthy siblings of juvenile myoclonic epilepsy patients compared to that of patients with juvenile myoclonic epilepsy?

### Study design

A total of three groups will be measured.

- 30 JME patients
- 30 healthy siblings of patients with epilepsy

In each subject a brief neuropsychological assessment is conducted with the following tests:

1. Trail making test

2 - Cognition in patients with Juvenile Myoclonus Epilepsy and their first degree he ... 5-05-2025

2. Word fluency test / woordopnoemen
3. Stroop Test
4. Digit span / Digit
5. I7 Impulsivity test

### **Study burden and risks**

The neuropsychological tests will take about half an hour.

## **Contacts**

### **Public**

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Achterweg 5  
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NL

### **Scientific**

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Achterweg 5  
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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)  
Elderly (65 years and older)

## Inclusion criteria

In generally good health  
Normal cognitive functioning (IQ>80)  
Speaking and reading Dutch  
Diagnosis of JME confirmed  
Older than 12 years

## Exclusion criteria

Any major neurological condition other than JME  
Any psychiatric condition (Axis I, Axis II)

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	24-08-2015
Enrollment:	60
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	20-11-2015

Application type: First submission  
Review commission: METC Leids Universitair Medisch Centrum (Leiden)

## 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	NL53705.058.15