

# Children exposed to antiepileptic drugs in utero: developmental and behavioral effects in primary school children

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON41629

### Source

ToetsingOnline

### Brief title

EURAP & Development

### Condition

- Other condition
- Cognitive and attention disorders and disturbances
- Family issues

### Synonym

development, mental health

### Health condition

gedragsproblemen

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universiteit van Amsterdam

**Source(s) of monetary or material Support:** Financiering uit een particulier legaat (Stichting Panta Rhei) voor kwetsbare kinderen

## Intervention

**Keyword:** antiepileptic drugs, children, epilepsy, pregnancy

## Outcome measures

### Primary outcome

Primary study parameters are: (1.) Verbal IQ, Performat IQ, Total IQ

(Intelligence: parents and child), attention, language skills, visuospatial

skills, fine motor skills, memory recall and learning (cognitive skills) and

social perception (theory of mind and affect recognition (kind), word finding

difficulties and receptive vocabulary (kind). (2). Child psychiatric outcome,

child behavioral outcome (including anxiety and depression), ADHD, and autism.

### Secondary outcome

Parenting stress, quality of parent-child relationship, parental behavior, and parenting

## Study description

### Background summary

Children exposed to antiepileptic drugs in utero are at higher risk for congenital malformations such as cardiac disease or spina bifida. Long-term effects on child neurocognitive and behavioral outcome are however hardly known.

### Study objective

Purpose of the study is to investigate neurocognitive and behavioral development in children of mothers with epilepsy, primary school age, and who were exposed to anti-epileptic drugs in utero. Primary research questions are: 1. what is the nature and severity of developmental problems (cognitive and behavioral) in children at ages 6/7 and at follow-up at ages 8/9? 2. What is the nature and severity of child developmental problems in children at ages 8/9 when compared to children at ages 6/7? 3. Which factors explain developmental problems in these children?

## **Study design**

Design of the study is prospective, observational and longitudinal. The study consists of two measurement waves: T1, if children are aged 6/7 years and T2, if children are aged 8/9 years. Between T1 and T2 are two years. Children, mothers, and fathers are asked to participate in the research by conducting neuropsychological tests (e.g., IQ test), and questionnaires (e.g. into behavioral problems such as autism or attention deficit disorder and parenting). The research is carried out at Epilepsy Institute in the Netherlands Foundation (SEIN), department of Psychology.

## **Study burden and risks**

The burden associated with participation is minimal. One appointment is made with children, mothers, and fathers: a visit of the family to the outpatient clinic of SEIN. A second appointment with parents will be made to discuss the results with parents. Associated risks are considered as minimal and the research is not painful neither invasive of nature. Parents and children are asked prior to study inclusion for written informed consent.

## **Contacts**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

### Inclusion criteria

- \*the study will aim at enrolling mother - child pairs meeting the eligibility criteria outlined below and enrolled semi-prospectively in the participating centres in the EURAP core study
- \*eligibility must be checked with the central registry in Milan (Dina Battino or Bibiana, email dbattino@istituto-besta.it) before enrolling the mother -child pair for NCEP (to avoid enrolling cases that have been rejected by the central registry prior to NCEP) for minimising selection bias
- \*every effort will be made to enroll all consecutive mother - child pairs and information about the reason for not enrolling will be recorded and analyzed to minimise the possible selection bias
- \*written informed consent will be required from the mother and /or father according to national legal requirements
- \*exposure of the child to CBZ, LTG, VPA or LEV monotherapy during the entire period from conception to birth
- \*exposed children are 6 / 7 years at T1
- \*exposed children are 8 / 9 years at T2

### Exclusion criteria

- \*mother\*s inability to take care of the child (e.g. due to severity of the epilepsy)
- \*known chromosomal/genetic syndromes of the child or prematurity (gestational age less than 37 weeks)
- \*mother - child pairs in whom information to estimate the impact of factors other than AED exposure modifying significantly development of the child cannot be reliably assessed, i.e. is missing or unavailable

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 05-01-2015

Enrollment: 780

Type: Actual

## Ethics review

Approved WMO

Date: 16-09-2014

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 13-02-2015

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**

ID: 27933  
Source: NTR  
Title:

**In other registers**

Register	ID
CCMO	NL45505.018.13
OMON	NL-OMON27933