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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	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, Performal 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 spinia bifida. Long-terms 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 morthers 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. Wat 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 of 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 chidlren, mothers, and fathers: a visit of the family to the outpatient clinic of SEIN. An second appointment with parents will be made to discuss the results with parents. Associated risks are considered as minimal and the research is nor 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: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45505.018.13
OMON	NL-OMON27933