EURAP & Development

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27933

Source
NTR

Brief title
EURAP- NCEP: Eurapean Register of Antiepileptic Drugs and Pregnancy - Neurocognitive extension protocol

Health condition

Children of mothers with epilepsy exposed to antiepileptic drugs in utero

Sponsors and support

Primary sponsor: Stichting Epilepsie Instellingen Nederland (SEIN) / University of Amsterdam (UvA)
Source(s) of monetary or material Support: private funding for vulnerable children: Stichting Panta Rhei

Intervention

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 , word finding difficulties and receptive vocabulary. (2) Child psychiatric outcome, child behavioral

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

Secondary outcome

Parenting stress, quality of parent child relationship, and parenting.

Study description

Study objective

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.

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 (carbamazepine, lamotrigine, valproate or levetiracetam) in utero.
Design of the study is prospective, observational and longitudinal. The study consists of two measurement waves: T1, when children are aged 6/7 years and T2, when 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 and questionnaires.

This study is partly based on the neurocognitive extension protocol (NCEP) and contributes to international knowledge on long term effects of exposure to antiepileptic drugs in utero.

Study design

Children exposed to antiepileptic drugs in utero and their mothers and fathers will get a neuropsychological assessment when the child is 6/7 years of age (T1) and again two years later when the child is 8/9 years of age. The neuropsychological assessment consists of an intelligence test for both children (Wechsler Intelligence Scale for Children: WISC-II-NL) and mothers and fathers (Wechsler Adult Intelligence Scale: WAIS-III-NL). Neurocognitive assessments for the child (A Developmental NEuroPSYchological Assessment: NEPSY-II-NL, Peabody Picture Vocabulary Test: PPVT-III-NL, verbal fluency test: Lindeboom) and behavioral questionnaires (Child Behavior Checklist: CBCL, Sociaal Emotionele Vragenlijst: SEV) and parenting questionnaires (Vragenlijsten Gezin & Opvoeding: VG&O, Ouder en kind interactie vragenlijst: OKIV-R) for parents.

Intervention

Neuropsychological testing

260 children (260 mothers and 260 fathers)

(test leaders will be blinded for type of antiepileptic drug taken by the mother with epilepsy during pregnancy)

Contacts

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Scientific
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Eligibility criteria

Inclusion criteria

-the study will aim at enrolling mother – child pairs meeting the eligibility criteria outlined below and enrolled semi-prospectively in the EURAP core study

-eligibility must be checked with the central registry in Milan before enrolling the mother-child pair for NCEP (to avoid enrolling cases that have been rejected by the central registry prior to NCEP) for minimizing 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 minimize the possible selection bias

- written informed consent will be required from the mother and /or father

-exposure of the child to Carbamazepine (CBZ), Lamotrigine (LTG), Valproate (VPA) or Levetiracetam (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 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
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2014
Enrollment:	260
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-09-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41629
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4657
NTR-old	NTR4800
CCMO	NL45505.018.13
OMON	NL-OMON41629

Study results