

EURAP & Development

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27933

Bron

Nationaal Trial Register

Verkorte titel

EURAP- NCEP: European Register of Antiepileptic Drugs and Pregnancy - Neurocognitive extension protocol

Aandoening

Children of mothers with epilepsy exposed to antiepileptic drugs in utero

Ondersteuning

Primaire sponsor: Stichting Epilepsie Instellingen Nederland (SEIN) / University of Amsterdam (UvA)

Overige ondersteuning: private funding for vulnerable children: Stichting Panta Rhei

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2014
Aantal proefpersonen:	260
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 22-09-2014

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41629

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten