Neuropsychological functioning and behavior of children previously treated with propranolol or atenolol for infantile hemangioma

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Differences between children treated with propranolol and atenolol for infantile hemangioma on the neuropsychological and behavioral outcome measures

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

Samenvatting

ID

NL-OMON29448

Bron
Nationaal Trial Register

Verkorte titel
Project Beta

Aandoening

Infantile Hemangioma

Ondersteuning

Primaire sponsor: Erasmus University Medical Center
Overige ondersteuning: Unrestricted grant provided by Pierre Fabre Dermatologie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Wechsler Intelligence Scale for Children-V-NL (WISC-V-NL) Cognitive Proficiency Index (a measure of working memory, attention and processing speed)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Since 2008, propranolol has been the first-choice treatment for infantile hemangioma (IH). Due to its lipophilic character, it has been suggested that propranolol might have negative effects on central nervous system functioning. Infants with IH receive propranolol at an age associated with extensive neuropsychological development, especially in the brain. Therefore, we expect that lipophilic beta blockers, such as propranolol, have a long-term impact on the neurodevelopment of children with IH. Non-lipophilic beta blockers, such as atenolol, are expected to have a different impact on the neurodevelopment of children treated for IH.
Objective: The main objective of this study is to be informed about the long-term effects of treatment with beta-blockers on the neuropsychological functioning and behavior of children treated with propranolol or atenolol for IH.
A secondary objective is to identify whether (long-term) follow-up is necessary for children who received beta blockers for IH during their first year of life.
Finally, we aim to be informed about the long-term cosmetic effects of propranolol treatment compared to atenolol treatment.
Study design: The study is cross-sectional and observational. Patients previously treated with atenolol for infantile hemangioma are compared to patients previously treated with propranolol for infantile hemangioma at the age of six or older. The psychologist who carries out the neuropsychological assessment is not informed about the type of beta blocker treatment (i.e. atenolol or propranolol) the participating children received until after completion of the study.
Study population: Children aged six or older who were previously treated for IH with beta blockers atenolol or propranolol at the Erasmus University Medical Center or the University Medical Center Utrecht.

Doel van het onderzoek

Differences between children treated with propranolol and atenolol for infantile hemangioma on the neuropsychological and behavioral outcome measures

Onderzoeksopzet

T1: a (neuro)psychological, pediatric and dermatologic assessment

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• IH previously treated either with oral propranolol at a ≥ 2 mg/kg/day dose or with oral atenolol at a ≥ 1 mg/kg/day dose.
• Treatment being initiated before the age of 1 year.
• IQ estimated > 55 (no moderate to severe intellectual disability)
• Sufficient comprehension of the Dutch language by parent(s)/legal guardian(s) to understand the study information and to be able to fill out the Dutch questionnaires.
• Sufficient comprehension of the Dutch language by the child to be able to participate in the neuropsychological assessment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Prematurity (< 37 weeks of gestation)
• Dysmaturity (birth weight <2.5 SDS for age)
• Complicated neonatal phase with hospitalization
• Suspected PHACE syndrome

• IH having received other treatment than oral propranolol or atenolol, such as other oral beta-blockers, oral corticosteroids, vincristine, interferon alpha, topical beta blockers, intralesional corticosteroids, imiquimod, rapamycin, laser, surgery, cryotherapy
• Documented (neuro-) psychological functioning problems before starting with beta blockers
• Use of medication that could affect (neuro-) psychological functioning (including multiple general anesthesia)
• Genetic syndromes known to affect cognitive performance
• Concomitant or successive use of propranolol and atenolol
• Participation to a previous clinical development study or Compassionate Use Program (CUP) with V0400SB
Next to this, all other possible confounders compromising neurocognitive function will be recorded at inclusion.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	10-05-2019
Aantal proefpersonen:	108
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	28-04-2019

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7703
Ander register	Non-WMO: METC Utrecht & METC Erasmus MC : 19/155 (METC Utrecht) / MEC-2019-0268 (METC Erasmus MC)

Resultaten