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

No registrations found.

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

Summary

ID

NL-OMON29448

Source
NTR

Brief title
Project Beta

Health condition

Infantile Hemangioma

Sponsors and support

Primary sponsor: Erasmus University Medical Center
Source(s) of monetary or material Support: Unrestricted grant provided by Pierre Fabre Dermatologie

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Neuropsychological outcomes:
- WISC-V-NL total intelligence quotient
- Rey's Auditory Verbal Learning Test (RAVLT)
- Developmental Neuropsychological Assessment-II-NL (NEPSY-II-NL): Visual-Spatial Memory
- NEPSY-II-NL: Affect Recognition
- NEPSY-II-NL: Narrative Memory

Psychological outcomes (parent-reported):
- Child Behavioral Checklist (CBCL)
- Behavior Rating Inventory of Executive Functioning (BRIEF)
- Health Related Quality of Life Questionnaire for Children and Young People and their Parents (KIDSCREEN)
- Parental Burden of Raising Children (OBVL)
- Questions exploring stress and support experienced during and after treatment of IH

Residual IH lesion:
- Child-reported Visual Analogue Scale (VAS)
- Clinician-reported Visual Analogue Scale (VAS)
- Parent-reported Patient and Observer Scar Assessment Scale (POSAS) Patient scale
- Clinician-reported Patient and Observer Scar Assessment Scale (POSAS) Observer scale
- Clinician-reported Hemangioma Activity Score (HAS)
- Clinician-reported checklist of residual lesion characteristics

Study description

Background summary

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.

Study objective

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

Study design

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-05-2019
Enrollment:	108
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-04-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results