Intellectual Disability and Epilepsy in Adults: cognitive trajectories and targets for care and interventions

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To investigate the trajectories of cognitive and adaptive functioning in adults with epilepsy and ID. In doing so we are looking for clinical determinants of cognitive and adaptive decline. Furthermore, the association between decline and serum...

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

Samenvatting

ID

NL-OMON26561

Bron
NTR

Verkorte titel
IDEA

Aandoening

Intellectual disability, epilepsy, Fragile X Syndrome, Angelman Syndrome, Tuberous Sclerosis Complex, Dravet Syndrome due to SCN1A mutations

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Epilepsiefonds, 's Heeren Loo

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Study 1 will have two main outcomes:
1) The difference in adaptive functioning (as measured with the Vineland Adaptive Behavior Scale-II (VABS-II)) when the outcomes of the TRIANGLE study are compared to the outcomes of the current study.
2) The relationship between changes in adaptive functioning and serum levels of neurofilament light chains.
Study 2 will have one main outcome:
1) The relationship between changes in adaptive functioning and serum levels of neurofilament light chains in the different genetic syndromes.

Toelichting onderzoek

Achtergrond van het onderzoek

Cognitive decline is a major clinical concern in adults with ID and epilepsy. It is thought to occur in the context of a 'chronic accumulation model' in chronic and refractory epilepsies; the effects of seizures, medication and ageing on an already vulnerable brain. However, epidemiology, phenomenology and determinants of cognitive decline are unknown as this vulnerable population is under-researched. In the earlier study TRIANGLE (MEC 2016-408) cognitive and adaptive functioning in a group of patients with epilepsy and intellectual disability was studied. By repeating the same measures we can compare the outcomes over time and study the cognitive trajectory in people with intellectual disability. Furthermore, a group of participants with differing genetic syndromes are studied for the first time. As patients with these syndromes have various degrees of epilepsy and intellectual disability, we can study the relationship between these factors and cognitive and adaptive functioning. By adding a blood analysis, we can study whether a possible decline in adaptive or cognitive functioning is associated with signs of neurodegeneration.
Additionally, use of serum biomarkers could eventually lead to a less burdensome way of evaluating dementia symptoms, in comparison with lumbar puncture and MRI-scans

Doel van het onderzoek

To investigate the trajectories of cognitive and adaptive functioning in adults with epilepsy and ID. In doing so we are looking for clinical determinants of cognitive and adaptive decline. Furthermore, the association between decline and serum biomarkers for dementia is explored.

Onderzoeksopzet

Study 1 is a follow-up 5 years after the TRIANGLE study
Study 2 is a cross-sectional study and thus will have only 1 time point.

Contactpersonen

Publiek

Erasmus MC / 's Heeren Loo
Malu van Schaijk

0622707068

Wetenschappelijk

Erasmus MC / 's Heeren Loo
Malu van Schaijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Study 1: Having participated in the earlier study TRIANGLE
Study 2: Be over the age of 18 and have a genetically confirmed diagnosis of one of following four syndromes;
Fragile X Syndrome, Tuberous Sclerosis Complex, Angelman Syndrome, SCN1A mutations

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Across both studies: No informed consent given by legal representative or the subject (if legally capacitated)
Study 2: An additional genetic diagnosis

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	285
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	05-05-2021
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	NL9455
Ander register	METC Erasmus MC : MEC-2020-0897

Resultaten