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

No registrations found.

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

Summary

ID

NL-OMON26561

Source
Nationaal Trial Register

Brief title
IDEA

Health condition

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

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Epilepsiefonds, 's Heeren Loo

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary study parameters include:
The neuropsychological outcome measures:
- Measure of cognitive problems such as memory and intelligence;
- Severity of affective symptoms (including depressive and anxiety symptoms); and other behavioral symptoms

Study description

Background summary

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

Study objective

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.

Study design

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.

Contacts

Public
Erasmus MC / 's Heeren Loo
Malu van Schaijk

0622707068
Scientific
Erasmus MC / 's Heeren Loo
Malu van Schaijk

0622707068

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2021
Enrollment:	285
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	05-05-2021
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	NL9455
Other	METC Erasmus MC : MEC-2020-0897

Study results